UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
NORFOLK DIVISION

IN RE: ZETIA (EZETIMIBE) ANTITRUST LITIGATION	Case No. 2:18-md-2836
THIS DOCUMENT RELATES TO: *United Healthcare Services, Inc., v. Merck & Co., Inc., et al.*, No. 2:20-cv-01005	**AMENDED COMPLAINT** JURY TRIAL DEMANDED

PLAINTIFF UNITED HEALTHCARE SERVICES, INC.'S AMENDED COMPLAINT[1]

[1] Originally filed in the United States District Court for the District of Minnesota, Case No. 20-cv-01909, transferred to this District for consolidated pretrial proceedings, subject to remand rights.

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Plaintiff United HealthCare Services, Inc. ("Plaintiff" or "UHS"), by and through its undersigned attorneys, brings this antitrust action against Defendants Merck & Company, Inc., Merck Sharp & Dohme Corporation, Schering-Plough Corporation, Schering Corporation, and MSP Singapore Company LLC (collectively, "Merck"), as well as Glenmark Pharmaceuticals, Limited and Glenmark Pharmaceuticals Inc., USA (collectively, "Glenmark"), and alleges as follows:

I. INTRODUCTION

1. This civil antitrust action challenges and seeks to redress an unlawful reverse-payment agreement between Merck and Glenmark that was intended to, and did, prevent lower-cost generic competition to Zetia, a first drug of a new class of lipid-lowering medications, and Vytorin, a fixed-dose combination pill comprised of Zetia and simvastatin (generic Zocor).

2. Pursuant to the reverse-payment agreement, Glenmark agreed to forego its meritorious patent challenge and delay its launch of generic Zetia for nearly five years in exchange for a payment from Merck in the form of Merck's promise not to launch an authorized generic version of Zetia that would compete with Glenmark's generic product during Glenmark's 180-day period of first-filer exclusivity. Par Pharmaceutical, Inc. ("Par") joined the agreement when it approved the unlawful reverse payment agreement and agreed to become the exclusive distributor of Glenmark's generic Zetia. Through this agreement Merck obtained billions of dollars of monopoly profits, and Glenmark/Par received hundreds of millions of dollars as a share of those profits, at the expense of purchasers, including UHS, who were deprived of the benefits of generic competition.

3. In the absence of the unlawful agreement between Merck and Glenmark/Par, both companies would have launched generic versions of Zetia as early as December 2011 and,

in any event, long before the actual entry date of December 12, 2016. Additional generics would have entered the market six months after Glenmark/Par. Plaintiff and other purchasers would have substituted lower-priced generic Zetia for higher-priced branded Zetia for the vast majority of their purchases of the drug. Similarly, Plaintiff and other purchasers would have substituted lower-priced generic Zetia and simvastatin for Vytorin.

4. Merck and Glenmark/Par's unlawful agreement violates Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1, 2, as well as Minnesota antitrust and consumer protection laws. UHS seeks civil damages for the overcharges it paid as a result of Defendants' conduct.

II. PARTIES

5. Plaintiff UHS is a corporation organized and existing under the laws of Minnesota with its principal place of business in Hennepin County, Minnesota. It is a wholly owned subsidiary of UnitedHealth Group, Inc. ("UHG"), which is also headquartered in Minnetonka, Minnesota.

6. UHS engages in servicing prescription drug managed care programs provided to members and beneficiaries under insurance plans offered by UHS's subsidiaries and affiliates, which, together, constitute the largest single health insurance carrier and services provider in the United States, and serve some 70 million individual insureds ("UnitedHealthcare Insureds").[2] UHS is the centralized and primary contracting entity responsible for payments made for prescription drugs dispensed to UnitedHealthcare Insureds throughout the country. From its headquarters in Hennepin County, Minnesota, UHS negotiated and executed contracts with Pharmacy Benefit Managers ("PBMs") on behalf of itself and its health plan subsidiaries

[2] For purposes of this Complaint, the term UnitedHealthcare Insureds does not include members of self-insured or self-funded health plans, also known as self-funded or Administrative Services Only ("ASO") customers.

and affiliates ("UnitedHealthcare Plans"), and during the relevant time period was (and is) contractually responsible for the payments made under those contracts, including for branded and generic Zetia and Vytorin dispensed to UnitedHealthcare Insureds during the relevant time period.

7. UHS is the parent company of, or otherwise an affiliate/related company to, each of the UnitedHealthcare Plans, which issue health insurance to UnitedHealthcare Insureds, including for coverage of prescription drug costs. The UnitedHealthcare Plans issue insurance to UnitedHealthcare Insureds covering prescription drugs in the form of (1) fully insured commercial ("Commercial") plans; (2) Medicare plans; and (3) Medicaid plans. The UnitedHealthcare Plans provide these prescription drug insurance benefits to UnitedHealthcare Insureds in all 50 states, the District of Columbia, and Puerto Rico. These UnitedHealthcare Plans are listed in the attached Exhibit A.

8. UHS is also an affiliate and the assignee of OptumRx Group Holdings, Inc., OptumRx, Inc., OptumRx Holdings, LLC, and their pharmacy subsidiaries (collectively, "Pharmacy Assignors") as pertaining strictly to the purchases made for or arising out of the business of the pharmacy subsidiaries. Pharmacy Assignors buy prescription drugs and dispense them to prescribed consumers, on a specialty and/or mail order retail pharmacy basis. Pharmacy Assignors have purchased substantial quantities of both branded and generic Zetia and Vytorin directly from Defendants, and have assigned to UHS their claims and the rights to obtain all recoveries arising out of such direct purchases and the matters/claims asserted in this Complaint.

9. UHS also brings this action as the assignee of claims from Cardinal Health, Inc. ("Cardinal"), which during the relevant period directly purchased Zetia, generic Zetia, and

Vytorin for resale to Pharmacy Assignors. Cardinal has assigned to OptumRx, Inc. its claims and the rights to all recoveries arising out of such direct purchases and the matters asserted in this Complaint, and OptumRx, Inc. in turn has assigned those claims and rights to UHS.

10. UHS seeks recovery for all unlawful overcharges it incurred in connection with indirectly paying for branded and generic Zetia and Vytorin products dispensed to UnitedHealthcare Insureds, including all those receiving insurance or health benefits from any of the UnitedHealthcare Plans (or their predecessors or successors). UHS also seeks recovery for all unlawful overcharges incurred in connection with the aforementioned direct purchases by Cardinal, as well as all direct purchases of such drug products by Pharmacy Assignors (together, "DP Assignors").

11. UHS is the proper entity to pursue all forms of relief, including damages, for all injury and losses incurred as alleged in this Complaint. Nonetheless, out of an abundance of caution, and to assure the Court that there is no potential for any duplicative indirect purchaser/payor recovery, UHS has obtained assignments from the UnitedHealthcare Plans, conveying to UHS any claims and rights to recoveries they may have in connection with the matters alleged in this Complaint. UHS hereby asserts those assigned indirect purchaser/payor claims in the alternative to the claims of UHS, to the extent that such assignors are found to be sole owners of any claims that are non-duplicative to those of UHS. Accordingly, to the extent that the Court were to find such assignments are required for any claims, all subsequent references to "UHS" include itself and assignors UnitedHealthcare Plans, unless expressly indicated otherwise.

12. Defendant Merck & Co., Inc. is a New Jersey corporation having its principal place of business at 2000 Galloping Hill Road, Kenilworth, New Jersey 07033. It is the parent

corporation of Defendants Merck Sharp & Dohme Corporation and MSP Singapore Company LLC.

13. Defendant Merck Sharp & Dohme Corporation is a New Jersey corporation having its principal place of business at 2000 Galloping Hill Road, Kenilworth, New Jersey 07033. It is a subsidiary of Defendant Merck & Co., Inc.

14. Defendant Schering-Plough Corporation was a New Jersey corporation having its principal place of business at 2000 Galloping Hill Road, Kenilworth, New Jersey 07033.

15. Defendant Schering Corporation was a New Jersey corporation having its principal place of business at 2000 Galloping Hill Road, Kenilworth, New Jersey 07033. It was a wholly owned subsidiary of Schering-Plough Corporation.

16. Merck & Co., Inc. acquired Schering-Plough Corporation in 2009. As part of that transaction, Merck & Co., Inc. merged into Schering-Plough Corporation, which subsequently changed its name to Merck & Co., Inc. The company formerly known as Merck & Co., Inc. changed its name to Merck Sharp & Dohme Corporation.

17. Defendant MSP Singapore Company LLC ("MSP") is a Delaware limited liability company having its principal place of business at 2000 Galloping Hill Road, Kenilworth, New Jersey 07033. MSP is a subsidiary of Merck & Co., Inc.

18. Defendant Glenmark Pharmaceuticals Limited is an Indian corporation having its principal place of business at Glenmark House, B.D. Sawant Marg, Andheri (E), Mumbai 400 099, India, and its registered office at B/2 Mahalaxmi Chambers, 22, Bhulabhai Desai Road, Mumbai 400 026, India.

19. Defendant Glenmark Pharmaceuticals Inc., USA is a Delaware corporation having its principal place of business at 750 Corporate Drive, Mahwah, New Jersey 07430. It is

a wholly owned subsidiary of Glenmark Pharmaceuticals Limited. Since 2002, when Glenmark Pharmaceuticals Inc., USA was incorporated, the company has been referred to, done business as, and/or been known as both Glenmark Pharmaceuticals Inc., USA and, at times, Glenmark Generics Inc., USA.

20. All of the actions attributed to Defendants in this Complaint were authorized, ordered and done by their respective officers, agents, employees or other representatives while actively engaged in the management of that Defendant's affairs and within the course and scope of their agency or employment, and/or with actual, apparent or ostensible authority.

III. JURISDICTION AND VENUE

21. The District of Minnesota has subject-matter jurisdiction over this action pursuant to 15 U.S.C. § 26, and 28 U.S.C. §§ 1331, 1332, and 1337.

22. The District of Minnesota has subject-matter jurisdiction over the state law claims alleged in this action pursuant to 28 U.S.C. § 1367, as the state law claims are so related as to form part of the same case or controversy. Such supplemental or pendent subject-matter jurisdiction will also avoid unnecessary duplication and multiplicity of actions, and should be exercised in the interests of judicial economy, convenience, and fairness. The court would also separately have jurisdiction over these claims under 28 U.S.C. § 1332(a), as the amount in controversy exceeds $75,000.00 and involves diversity of citizenship.

23. Venue is proper in the District of Minnesota pursuant to 15 U.S.C. § 22, and 28 U.S.C. § 1391. At all relevant times, Defendants resided, transacted business, and/or were found or had agents in the United States, including the District of Minnesota. During the alleged time period, Defendants marketed, sold and/or shipped one or more of the prescription drugs at issue in a continuous and uninterrupted flow of interstate commerce in the United

States, including into the District of Minnesota. Further, Defendant Merck Sharp & Dohme Corporation is registered to do business in the State of Minnesota, maintain designated agents for service of process in Minnesota, and employ sales and other personnel in the District of Minnesota. Defendants' conduct alleged herein had a direct, substantial, and reasonably foreseeable effect on interstate commerce in the United States, including in the District of Minnesota. Defendants' conduct in artificially increasing prices for the drug products at issue was directed at, and had the intended effect of causing injury to, persons residing in, located in, or doing business throughout the United States, including in the District of Minnesota specifically, and Defendants are otherwise subject to the service of process provisions of 15 U.S.C. § 22.

24. Defendants are subject to the personal jurisdiction of the District of Minnesota Court for one or more of the reasons stated below:

a. Defendants are subject to service of process for this action as provided in 15 U.S.C. § 22;

b. Defendants are amenable to service of process because, as alleged in this Complaint, they inhabit, transact business in, have continuous or systematic contacts with, and/or are found or have sufficient minimum contacts in the United States sufficient to satisfy due process. While Defendants are headquartered outside the District of Minnesota, they nevertheless engaged in the business of developing, distributing, advertising and/or selling the drug products at issue into the District specifically and purposefully.

c. Defendants are amenable to service of process pursuant to Rule 4(k)(1)(A) of the Federal Rules of Civil Procedure and the long-arm statute of the State in which the District of Minnesota Federal Court sits because, *inter alia*, and as alleged in this Complaint, Defendants have transacted business in the District and have contracted to supply services or things in the District, and because the District's long-arm statute extends jurisdiction to the limits of due process and Defendants has sufficient minimum contacts with the District to satisfy due process; and/or

d. Based on the allegations in this Complaint, Defendants are subject to the general and specific personal jurisdiction of the District of Minnesota Court because they have purposefully directed their contacts and conduct at the forum District and have purposefully availed themselves of the laws of the District. As alleged in this Complaint, Defendants engaged in anticompetitive conduct that was intended to have, and did have, direct, substantial and reasonably foreseeable effects on the commerce throughout the United States, including the District; and

e. Defendant Merck Sharp & Dohme Corporation is registered to do business in the State of Minnesota, and maintains designated agents for service of process within the State of Minnesota.

25. UHS originally filed this action in the United States District Court for the District of Minnesota, wherein it was assigned Case No. 20-cv-01909. UHS's case was then transferred to the United States District Court for the Eastern District of Virginia, Norfolk Division, by the

United States Judicial Panel on Multidistrict Litigation for consolidated pretrial proceedings. UHS has filed its Amended Complaint under the header of the above-captioned MDL proceeding pursuant to ECF No. 20 and ECF No. 1488. UHS expressly reserves its remand rights under *Lexecon v. Milberg Weiss Bershad Hynes & Lerach*, 523 U.S. 26 (1998).

IV. BACKGROUND

A. The Regulatory Structure for the Approval of Generic Drugs and the Substitution of Generic Drugs for Brand Name Drugs

26. Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), manufacturers that create a new drug must obtain FDA approval to sell the product by filing a New Drug Application ("NDA"). 21 U.S.C. §§ 301-392. An NDA must include specific data concerning the safety and effectiveness of the drug, as well as any information on applicable patents. 21 U.S.C. § 355(a), (b).

27. When the FDA approves a brand-name manufacturer's NDA, it lists in a publication titled the "Approved Drug Products with Therapeutic Equivalence Evaluations" (known as the "Orange Book") any patents which, according to the information supplied to the FDA by the brand-name manufacturer: (1) claim the approved drug or its approved uses; and (2) for which a "claim of patent infringement could reasonably be asserted if a person is not licensed by the owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C. §§ 355(b)(1) & (c)(2). The manufacturer may subsequently list in the Orange Book within thirty days of issuance any such patents issued after the FDA approves the NDA. 21 U.S.C. §§ 355(b)(1) & 355(g)(7)(A)(iii).

28. The FDA relies completely on the brand manufacturer's truthfulness about patent validity and applicability, as it does not have the resources or authority to verify the

manufacturer's patents for accuracy or trustworthiness. In listing patents in the Orange Book, the FDA merely performs a ministerial act.

B. The Hatch-Waxman Act and ANDA Approval Process

29. In 1984, Congress amended the FDCA through enactment of the Drug Price Competition and Patent Restoration Act, commonly known as the Hatch-Waxman Act. Congress's principal intent was for Hatch-Waxman to simplify and reduce regulatory hurdles for prospective generic manufacturers, by replacing the lengthy and costly NDA approval process through the filing of an Abbreviated New Drug Application ("ANDA"), to introduce competition into the marketplace.

30. An ANDA relies on the scientific findings of safety and effectiveness included in the brand manufacturer's original NDA, and must further show that the generic drug contains the same active ingredient(s), dosage form, route of administration, and strength as the brand drug and is absorbed at the same rate and to the same extent as the brand drug – that is, that the generic drug is pharmaceutically equivalent and bioequivalent[3] to the brand drug. The FDA assigns oral-dosage-form generic drugs that are pharmaceutically equivalent and bioequivalent to their brand-name counterpart an "AB" rating.

31. Congress enacted the Hatch-Waxman Amendments to expedite the entry of legitimate (non-infringing) generic competitors, thereby reducing healthcare expenses nationwide. Congress also sought to protect pharmaceutical manufacturers' incentives to create new and innovative products.

[3] Bioequivalence exists when the active ingredient of the proposed generic drug would be present in the blood of a patient to the same extent and for the same amount of time as the branded counterpart. 21 U.S.C. § 355(j)(8)(B).

32. The Hatch-Waxman Amendments achieved both goals, advancing substantially the rate of generic product launches, and ushering in an era of historically high profit margins for brand manufacturers.

C. Paragraph IV Certifications

33. To obtain FDA approval of an ANDA, a manufacturer must certify that the generic drug will not infringe any patents listed in the Orange Book. Under Hatch-Waxman, a generic manufacturer's ANDA must contain one of four certifications:

a. no patent for the brand drug has been filed with the FDA (a "Paragraph I certification");

b. the patent for the brand drug has expired (a "Paragraph II certification");

c. the patent for the brand drug will expire on a particular date and the manufacturer does not seek to market its generic product before that date (a "Paragraph III certification"); or

d. the patent for the brand drug is invalid or will not be infringed by the generic manufacturer's proposed product (a "Paragraph IV certification").

34. If a generic manufacturer files a Paragraph IV certification, a brand manufacturer can delay FDA approval of the ANDA simply by suing the ANDA applicant for patent infringement. If the brand manufacturer initiates a patent infringement action against the generic filer within forty-five days of receiving notification of the Paragraph IV certification ("Paragraph IV Litigation"), the FDA will not grant final approval to the ANDA until the earlier of: (a) the passage of 30 months, or (b) the issuance of a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA. Until one of those conditions occurs, the FDA may grant "tentative approval," but cannot authorize the generic manufacturer to market its product. The FDA may grant an ANDA tentative approval when it

determines that the ANDA would otherwise be ready for final approval but for the 30-month stay.

35. As an incentive to spur manufacturers to develop and seek approval of generic alternatives to branded drugs, Hatch-Waxman grants a 180-day period of market exclusivity to the first Paragraph IV ANDA applicant ("first filer") to file a substantially complete ANDA. During the 180-day exclusivity period (measured from the first commercial marketing of the generic drug or the date of a court decision finding the listed patent invalid, unenforceable, or not infringed, 21 U.S.C. § 355(j)(5)(B)(iv)), the first ANDA filer enjoys 180 days of freedom from competition from other generic versions of the drug (except in the case of an authorized generic as discussed below), and during that period effectively has a duopoly with the brand manufacturer.

36. To generic manufacturers, entering the market first with the 180-day exclusivity period is an important objective. Before generic entry, the brand drug is typically priced far above competitive levels. During the 180-day period of exclusivity, the generic price, while lower than the branded price, is still much higher than it would be in the presence of two or more generic competitors. Generics are usually at least 25% less expensive than their brand name counterparts when there is a single generic competitor, but this discount typically increases up to 80%, 90%, or more, when there are multiple generic competitors on the market. For a generic manufacturer, being able to sell at the higher duopoly price for 180 days may be worth hundreds of millions of dollars.

37. Under this regulatory scheme, NDA-holders have strong financial incentives to "game the system" by listing patents in the Orange Book, even if such patents are not eligible for listing because they are invalid or unenforceable, and by suing any generic competitor that

files an ANDA with a Paragraph IV certification, even if the generic competitor's product does not actually infringe the listed patent because merely filing suit delays generic entry during the automatic 30-month stay.

38. Similarly, the first generic applicant can help the brand manufacturer "game the system" by agreeing to delay its own market entry, which effectively blocks the market entry of all generic manufacturers because later generic applicants cannot launch until the first generic applicant uses or forfeits its 180-day exclusivity period.

D. Benefits of Generic Drugs

39. Generic versions of brand name drugs contain the same active ingredient, and are determined by the FDA to be just as safe and effective as their brand-name counterparts. ANDAs for orally available solid dosage forms (tablets, capsules, etc.) that meet all of the requirements for FDA approval are assigned an "AB" rating by the agency. AB-rated generics are deemed by the FDA to be therapeutically equivalent and pharmaceutically equivalent to their brand-name counterparts.

40. An AB rating for a generic drug is significant. All states permit (and some states require) pharmacists to substitute an AB-rated generic version of a drug for the brand name drug without seeking or obtaining permission from the prescribing physician (unless the prescription is denominated "Dispense as Written").

41. Many third-party payors, such as Plaintiff, whose members account for a substantial share of purchases in the market, have adopted policies to encourage the substitution of lower-cost AB-rated generic drugs for their branded counterparts. As Merck explained in its Annual Report, "Loss of patent protection for one of the Company's products

typically leads to a significant and rapid loss of sales for that product, as lower priced generic versions of that drug become available."[4]

42. During the relevant time period, UHS developed and distributed Prescription Drug Lists ("PDLs"), sometimes referred to as formularies. With the thousands of drugs available at any point in time, and more coming to market every day, UHS examines how many new drugs may cost more yet offer no additional health benefit. UHS's PDLs promote medications with the greatest health care value to UnitedHealthcare Insureds, regardless of brand or generic status. Every drug is evaluated to determine how well it works, how it compares to others in its class, the total cost, and a number of other significant considerations to make sure that the medications with the highest health care value are affordable for plan participants. UHS uses this information to then organize all brand and generic prescription drugs into tiers on a PDL. The PDLs are developed with input from a number of groups within UHS, including internal clinical subject matter experts ("SMEs") responsible for developing, managing, updating, or administering PDLs or PDL system policies. UHS's SMEs recommend drugs for plan coverage on the basis of clinical evidence and relevant findings from appropriate sources of information. Drug coverage decisions are then made by SMEs, which ultimately determine the assignment of approved prescription drug products to a particular PDL tier. The placement of particular drug products on UHS's PDL affects the out-of-pocket costs owed by UnitedHealthcare Insureds.

43. UHS's benefit design is focused on optimizing health outcomes in addition to reducing costs for drug products and providing UnitedHealthcare Insureds affordable health care options. What a UnitedHealthcare Insured pays for prescription drugs is influenced by the

[4] *See, e.g.,* Merck & Co., Inc. Form 10-K for the Fiscal Year Ended 2016 at 18.

PDL tied to a member's plan. Under the plan design and PDL placement, an insured is subject to either a copayment, coinsurance or no cost at all. Generally speaking, drugs that provide lower cost and the highest overall health care value are placed on Tier 1, which includes mostly generic drugs. Tier 1 drugs have the lowest out-of-pocket costs for UnitedHealthcare Insureds' members. Drugs contained on Tier 2 and Tier 3 typically provide good value and include a mix of brand-name drugs and generic drugs. Tier 2 and Tier 3 drugs have lower out-of-pocket costs than Tier 4 drugs. Drugs on Tier 4 generally have the highest costs and may have lower cost clinical alternatives available to UnitedHealthcare Insureds on Tiers 1, 2, and/or 3. UHS distributes its PDLs to physicians to function as a guide for physicians to use when selecting the most appropriate medication(s) with the lowest member cost-sharing obligation for their patients. Physicians regularly use such information when prescribing medication for their insured patients.

44. When UHS determines that drug products are therapeutically equivalent (meaning, they provide the same outcomes with the same side effects), it may make PDL coverage decisions that essentially encourage the use of the lower-net cost options since the drugs were already determined to provide the same health benefits. UHS, like other payors, has a number of programs it can institute to encourage its insureds to seek, and physicians to write prescriptions for, lower-cost drugs that provide equivalent health benefits. Examples of such programs include requiring prior authorizations with the input of the prescribing physician, imposing step therapy (essentially a try/fail requirement), or excluding coverage of overpriced drugs altogether when one or more lower cost alternatives is available.

45. As with other payors, UHS's policies and programs can help influence the behavior of insureds and physicians and lower UHS's total prescription drug costs, as well as

the costs to UnitedHealthcare Insureds. Physicians are sensitive to coverage decisions and the cost of medications for their insured patients and take into account formulary status and other factors that might increase their patients' out-of-pocket costs. UnitedHealthcare Insureds are also highly sensitive to cost and will typically seek the covered option with the lowest out-of-pocket cost, holding all else equal.

46. As Merck stated in one public filing, formulary placement was "critical" to Zetia's success because "the overwhelming majority of Zetia sales occur through formularies" and "inferior formulary treatment" would lead to a loss of sales. Merck has also acknowledged that clinicians considered price in making their prescribing decisions concerning Zetia.[5]

47. Until a generic manufacturer enters the market with an AB-rated generic product, there is no bioequivalent generic drug which competes with the brand-name drug and the brand name manufacturer can continue to charge supra-competitive prices profitably without losing all or a substantial portion of its brand-name sales. That monopoly allows brand manufacturers to charge prices far above competitive levels (i.e., above the prices that prevail for that drug upon generic entry) without losing all or a substantial portion of their brand drug sales.

48. The launch of a generic drug creates price competition that provides cost savings for all purchasers of the drugs. When an AB-rated generic enters the market, it quickly captures sales of the corresponding branded drug, often capturing 80% or more of the market within the first six months. The Federal Trade Commission ("FTC") has estimated that, within a year of the first generic entrant, the generic version on average takes over 90% of the brand's

[5] Defendants' Opposition to Plaintiffs' Motion for Partial Summary Judgmeent Concerning the Relevant Market & Motion to Exclude the Proposed Testimony of Dr. Anupam B. Jena, Public Version, ECF No. 1140 at ¶¶ 10, 11, p. 30-32

unit sales and sells for 15% of the price of the brand name product. Prices for the generic drugs typically decline further as more generic companies compete with one another. As a result, brand name companies, such as Merck, view competition from generic drugs as a grave threat to their profits.

E. The Impact of Authorized Generics

49. The 180-day marketing exclusivity for first-filers does not prevent a brand manufacturer from marketing its own generic alternative to the brand drug during the exclusivity period, pursuant to its own approved NDA. Such an "authorized generic" is identical to the brand drug, but is sold as a generic product either by the brand manufacturer itself or through an authorized third party. Competition created by an authorized generic during the 180-day exclusivity period leads to lower prices for generic drugs and a decrease in brand name sales.

50. In its study *Authorized Generic Drugs: Short-term Effects and Long-Term Impact* (August 2011), the FTC found that authorized generics capture a significant portion of sales, reducing the revenues generated by the first-filer's generic product by 40-52% during the 180-day exclusivity period. The first-filing generic makes significantly less money when it faces competition from an authorized generic because (1) the authorized generic takes a large share of unit sales away from the first-filer; and (2) the presence of an additional generic in the market leads to lower overall generic prices. This competition benefits drug purchasers. Conversely, the lack of such competition harms purchasers by reducing choice and increasing prices.

51. As a practical matter, authorized generics are the only means by which brand-name manufacturers engage in price competition with manufacturers of AB-rated generic drugs.

Brand-name manufacturers generally do not reduce the price of their branded drug in response to the entry of an AB-rated generic. Instead, during the relevant time period, brand manufacturers typically raised the brand-name price to extract higher profits from the small number of "brand-loyal" patients.

F. The Economics of Reverse-Payment Agreements

52. Reverse-payment agreements arise in response to the threatened loss of exclusivity from patent challenges by generic drug makers. Reverse-payment agreements interrupt the well-worn process by which generic drug competition reduces drug prices. In a reverse-payment agreement, the brand pays the generic (the alleged patent infringer) to dismiss its patent challenge and forego generic entry for a period of time.

53. From an economic perspective, there is reason to scrutinize any reverse-payment agreement because it arises in a unique context. In Hatch-Waxman litigation, the generic firm does not claim damages from the brand company that owns the patent. Thus, a typical reason for a settlement payment – to compensate for damages that have allegedly accrued – does not exist. Thus, the very existence of the payment is an unusual feature of the agreement that requires explanation and invites careful scrutiny.

54. Absent the deterrence effect of antitrust law, reverse-payment agreements would be economically rational for both the branded drug maker and the generic manufacturer. By delaying generic entry, the branded manufacturer preserves a stream of supranormal profits. The branded manufacturer can use those profits to pay the generic manufacturer more than the generic manufacturer would have earned had it entered the market and competed against the branded manufacturer's product and any subsequent generic entrants. Although both drug companies profit from that arrangement, they do so at the expense of drug purchasers who pay

those monopoly profits and are deprived of the benefits of competition, including the opportunity to purchase lower-priced generics.

55. Reverse-payment agreements that include an agreement by the branded manufacturer not to launch an Authorized Generic ("no-AG" provision) are even more harmful to competition than reverse-payment agreements involving only a cash transfer because, unlike cash payments, no-AG provisions delay generic entry and continue to restrict competition even after generic entry by eliminating competition between the generic manufacturer's product and the authorized generic. The profits used by the branded manufacturer to compensate the generic manufacturer in a no-AG provision come from the pockets of purchasers (including Plaintiff) who would otherwise pay the drug companies less in the absence of the no-AG agreement.

V. CHOLESTEROL-LOWERING DRUGS

56. Cholesterol is essential in constructing and maintaining membranes in animal cells. It makes up part of the myelin sheath that insulates nerve cells and facilitates conducting nerve impulses. It is also an important precursor for making vitamin D and steroid hormones in the body.

57. Our bodies derive cholesterol from two sources. We make cholesterol, mostly in our livers. We also absorb cholesterol through our intestines. This absorption includes both cholesterol from the foods we eat and the cholesterol we make. About 50% of the cholesterol made in our livers is reabsorbed through our intestines.

58. There are two types of cholesterol: LDL (low-density lipoprotein) and HDL (high-density lipoprotein). LDL cholesterol is known as "bad" cholesterol because, in high plasma concentrations, it promotes the development of atherosclerosis. LDL cholesterol is produced by a protein in the liver, HMG-CoA reductase. HDL cholesterol is known as "good"

cholesterol because, in high plasma concentrations, it helps prevent the development of atherosclerosis.

59. Coronary heart disease (CHD), a manifestation of atherosclerosis, is the leading cause of death in the US. Hypercholesterolemia, excessive LDL cholesterol in in the blood stream, is a major modifiable risk factor for the development of CHD. A 1% reduction in total cholesterol is estimated to decrease the incidence of CHD by approximately 2%.

A. The Development of Statins

60. In the 1970s and '80s, scientists discovered a group of cholesterol-lowering drugs known as statins. Statins lower cholesterol levels by inhibiting the enzyme that regulates the production of LDL cholesterol in the liver. In 1987, Merck launched the first statin, Mevacor (lovastatin). Merck later launched a second statin, Zocor (simvastatin). Zocor was a blockbuster drug for Merck. Other drug companies – including Sankyo, Novartis, Pfizer, and AstraZeneca – followed suit.

61. Statins, as a class, are the first-line treatment for patients with high LDL cholesterol and were for many years the most profitable drugs in pharmaceutical history. It has been estimated, however, that 60% of the 13 million patients receiving statins alone in the U.S. do not reach their target reduction in LDL cholesterol. Moreover, a subset of patients with high LDL-cholesterol suffer from statin intolerance, which means that statins cause them to suffer side effects and other problems, *e.g.,* muscle aches, pains, weakness, or cramps (often called myalgias), muscle inflammation (myositis) and markers of muscle injury (creatine kinase). For these patients, statins are not a meaningful treatment option.

B. Zetia and Vytorin: Merck's Cholesterol "Franchise" Drugs

62. Zetia is not a statin. It is a 2-azetidinone compound with a unique mechanism

of action. Zetia inhibits gastrointestinal absorption of dietary and biliary cholesterol and related phytosterols at the brush border of the small intestines. In other words, whereas statins reduce the synthesis of LDL cholesterol in the liver, Zetia inhibits the absorption of cholesterol in the small intestines. In patients with lipid disorders, Zetia reduces total and LDL cholesterol, apolipoprotein B, and triglycerides, and increases HDL cholesterol. Zetia is well tolerated with few reported side effects. Zetia was the first and only cholesterol absorption inhibitor approved by the FDA and commercially available.[6]

63. Zetia's unique mechanism of action complements statins. Combining Zetia with a statin improves lipid fractions in hyperlipidemia more than administration of either agent alone. Zetia in combination with a statin decreases LDL cholesterol by up to 25% more than statins alone. Adding Zetia to a low dose of a statin decreases LDL cholesterol at least as much as the maximum dose of a statin. In fact, in at least one study, the maximum dose of a statin was less effective in reducing LDL cholesterol than Zetia combined with a lower dose of the statin. In patients with homozygous familial hypercholesterolemia, Zetia reduces LDL cholesterol by an additional 14% to 21% over monotherapy with atorvastatin or simvastatin 40 mg to 80 mg. According to Merck, as of 2011 about half of Zetia prescriptions were for "statin-intolerant" patients and the other half were to complement statin prescriptions – in other

[6] In 2018, the FTC imposed conditions on the merger of Amneal Holdings, LLC and Impax Laboratories, Inc., to preserve competition in the market for generic Vytorin. In its analysis, the FTC determined that there was a "relevant market" for generic Zetia and simvastin IR tablets. https://www.ftc.gov/system/files/documents/cases/1810017_ amneal_impax_analysis_4-27-18.pdf. At the time, Amneal and Impax were two of four manufacturers of generic Vytorin. The FTC required Impax to supply another manufacturer with generic Vytorin for two years with an option for two additional years to preserve competition in that market.

words the patients were prescribed two pills -- Zetia and a statin.[7] Zetia and Vytorin are different ways of selling the same drug, ezetimibe. In a March 2014 article, Marvin Lipman, M.D., Consumer Reports' chief medical adviser referred to Vytorin as a "ploy" used by pharmaceutical companies to simply combine two drugs to produce a new patentable product.

64. Vytorin is a fixed-combination pill sold by Merck that combines Zetia and simvastatin. Vytorin is indicated as adjunctive therapy to diet to (1) reduce elevated LDL cholesterol, ApoB, TG, and to increase HDL-C in patients with primary (heterozygous familial and non-familial) hyperlipidemia or mixed hyperlipidemia or (2) reduce elevated total-C and LDL-C in patients with homozygous familial hypercholesterolemia (HoFH), as an adjunct to other lipid-lowering treatments.

65. Before their merger, Merck and Schering launched Zetia in 2002 as a partnership. Merck and Schering launched Vytorin in 2004. Merck and Schering merged in 2009. Together, Merck viewed Zetia and Vytorin as its "cholesterol franchise." At the time, they were among Merck's largest selling drugs. Internally, Merck determined pricing and marketing strategies for Zetia and Vytorin together to ensure alignment. In fiscal years 2014-16, Merck's combined global sales for Zetia and Vytorin were $4.17 billion ($2.65 billion Zetia, $1.52 billion Vytorin), $3.78 billion ($2.526 billion Zetia, $1.25 billion Vytorin), and

[7] Merck & Co.'s CEO Discusses Q3 2011 Results - Earnings Call Transcript. In that call, Merck's Executive Vice President and President of Global Human Health, Adam H. Schechter, told analysts that the availability of generic Lipitor would have a "minimal impact" on Zetia sales and pricing because patients who are statin-intolerant will not be affected "irrespective of Lipitor being on or off patent" and the "other half of the use is add-on to statins" where there's "no reason to believe that physicians will not add ZETIA to statins as much in the future as they have in the past, irrespective of what's happening with generic Lipitor." Zetia is also considered a first-line treatment for dyslipidemia and patients who are pregnant because Zetia is pregnancy category C and statins are category X.

$3.7 billion ($2.56 billion Zetia, $1.14 billion Vytorin), respectively.[8] In the U.S., sales for Zetia and Vytorin were $1.6 billion and $473 million, respectively, for fiscal year 2016. *Id.*

66. Branded Zetia was, by far, the largest cost component of Vytorin. For example, in November 2016, the wholesale acquisition cost ("WAC")—an estimate of the manufacturer's list price for a drug to wholsalers or direct purchasers— was $8.72/pill for Zetia, whereas the price of generic simvastatin was approximately $0.27/pill during that same time. That means Zetia comprised more than 95% of the cost of Vytorin.

67. Merck set Zetia prices "somewhat below" the price of Vytorin.[9] From at least 2014 through 2017, Merck maintained a very small price differential between Vytorin and Zetia. Merck had to keep Zetia prices close to Vytorin prices because a significant price gap would have incentivized buyers and third party payors to prefer a two-pill Zetia/simvastatin regimen over Vytorin.

68. At least as early as 2009, UHS's SMEs concluded that Vytorin was therapeutically equivalent to the combination of Zetia and simvastatin. That means that UHS could have gone as far as to exclude coverage of Vytorin if the combination of Zetia and simvastatin, prescribed separately, provided a lower cost alternative to Vytorin. Had generic Zetia been available some time before April 2017 at competitive prices, e.g. $0.21/pill, UHS would have excluded branded Vytorin from coverage or used other tools at its disposal described herein to ensure that it paid less for Vytorin than what it ultimately ended up paying over the relevant time period.

[8] *See* Merck Form 10-K at 37.

[9] Report and Recommendation, ECF No. 1391, at 7.

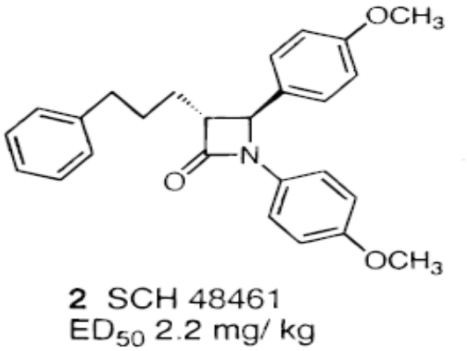
VI. THE ANTICOMPETITIVE CONDUCT

A. Early 1990s: Merck develops hydroxyl-substituted azetidinone compounds useful as hypocholesterolemic agents

69. In the early 1990s, Merck embarked on a broad chemical program to discover novel ACAT (acyl-CoA cholesterol acyltransferase) inhibitors as cholesterol-lowering and/or antiatherosclerotic agents. Scientists working in Schering's New Jersey facilities began developing azetidinone compounds to reduce cholesterol levels in humans. Those scientists included Stuart B. Rosenblum, Sundeep Dugar, Duane A. Burnett, John W. Clader, and Brian McKittrick.

70. In lab experiments conducted over two years or less, these scientists identified a lead compound, SCH48461, and inherent metabolites and metabolite-like analogues of that compound, including SCH58235 – ezetimibe. SCH 48461 is (3R,3S)-1,4-bis-(4-methoxyphenyl)-3-(3-phenylpropyl)-2-azetidinone.[10] It is pictured in Figure 1 below.

Figure 1. SCH 48461

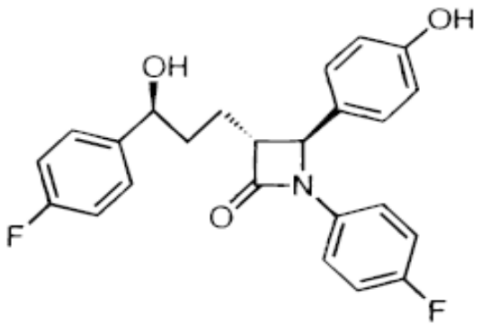


2 SCH 48461
ED_{50} 2.2 mg/ kg

[10] *See* Brian G. Salisbury, *Hypocholesterolemic Activity of a Novel Inhibitor of Cholesterol Absorption*, SCH 48461, 115 Atherosclerosis 45 (1995); Duane A. Burnett et al., *2-Azetidinones as Inhibitors of Cholesterol Absorption*, 37 J. Med. Chem. 1733 (1994).

71. SCH 58235 is 1-(4-fluorophenyl)-(3R)-[3-(4-fluorophenyl)-(3s)-hydroxypropyl]-(4S)-(4-hydroxypheyl)-2-azetidinone[11]. The use of halogen to block sites of metabolism was then well known. To create SCH 58235, Merck scientists used routine laboratory techniques to add fluorine to the two phenyl rings, in order to lessen the likelihood of hydroxylation (and thereby keep the compound in the body longer). It is pictured in Figure 2 below.

Figure 2. SCH 58235, Ezetimibe



1 SCH 58235
ED_{50} 0.04 mg/ kg

72. Upon discovering these and other useful compounds (and their metabolites), and recognizing their potential to be developed into lucrative prescription drugs down the road, Merck set out to obtain broad patent protection.

73. Merck knew that publishing journal articles about its research and development could potentially undermine its ability to patent its inventions. As a result, its scientists did not publish their discoveries until after the first patent application was filed and, in some instances,

[11] Stuart B. Rosenblum, *Discovery of 1-(4-Fluorophenyl)-(3R)-[3(4-fluorophenyl)-(3S)-hydroxpropyl]-(4S)-(4-hydroxphenyl)-2-azetidinone (SCH 58235): A Designed, Potent, Orally active Inhibitor of Cholesterol Absorption,* 41 J.Med. Chem. 973 (1998).

waited more than a decade after making its discoveries in the early 1990s before writing about the development process over a decade.[12]

B. 1993-1998: Merck applies for, and obtains, the original azetidinone patents (the '365, '115, and '966 patents)

74. Beginning in 1993, Merck filed a series of related U.S. patent applications addressing hydroxyl-substituted azetidinone compounds useful as hypocholesteremic agents.[13] Three issued as patents; one of these then reissued twice.

75. The family of patents resulting from these applications can be referred to as "the azetidinone patents." As shown in Figure 3 below, the azetidinone patents include the '365 patent, the '115 patent, the '966 patent, the RE'721 patent, and the RE'461 patent.

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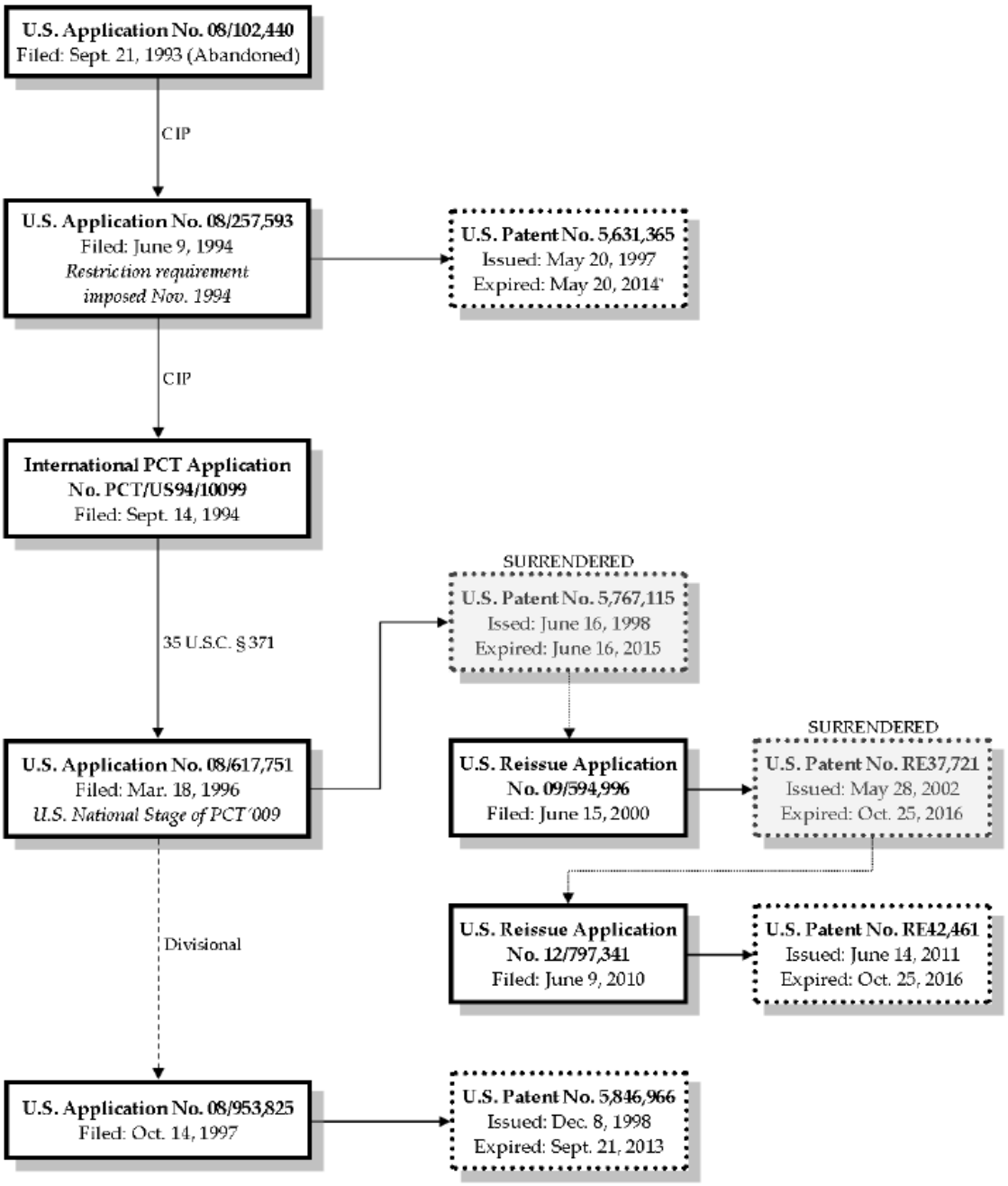
[12] *See* John W. Clader, *Ezetimibe and other Azetidinone Cholesterol Absorption Inhibitors*, 5 Current Topics Med. Chem. 243 (2005); John W. Clader, *The Discovery of Ezetimibe: A View from Outside the Receptor*, 47 J. Med. Chem. 1 (2004); Stuart B. Rosenblum et al., *Discovery of 1-(4-Fluorophenyl)-(3R)-[3-(4-fluorophenyl)-(3S)-hydroxypropyl]-(4S)-(4-hydroxyphenyl)-2-azetidinone (SCH58235): A Designed, Potent, Orally Active Inhibitor of Cholesterol Absorption*, 41 J. Med. Chem. 973 (1998); Margaret Van Heek et al., *In Vivo Metabolism-Based Discovery of a Potent Cholesterol Absorption Inhibitor, SCH58235, in the Rat and Rhesus Monkey through the Identification of the Active Metabolites of SCH 48461*, 283 J. Pharmacology & Experimental Therapeutics 157 (1997); Sundeep Dugar et al., *Metabolism and Structure Activity Data Based Drug Design: Discovery of (-) SCH 53079, an Analog of the Potent Cholesterol Absorption Inhibitor (-) SCH 48461*, 11 Bioorganic & Med. Chem. Letters 1271 (1996); John W. Clader et al., *2-Azetidinone Cholesterol Absorption Inhibitors: Structure-Activity Relationships on the Heterocyclic Nucleus*, 39 J. Med. Chem. 3684 (1996); Brian A. McKittrick et al., *Stereoselective Synthesis and Biological Activity of Cis Azetidinones as Cholesterol Absorption Inhibitors*, 16 Bioorganic & Med. Chem. Letters 1947 (1996); Brian G. Salisbury et al., *Hypocholesterolemic Activity of a Novel Inhibitor of Cholesterol Absorption, SCH 48461*, 115 Atherosclerosis 45 (1995); Sundeep Dugar et al., *Gamma-Lactams and Related Compounds as Cholesterol Absorption Inhibitors: Homologs of the β-Lactam Cholesterol Absorption Inhibitor SCH 48461*, 24 Bioorganic & Med. Chem. Letters 2947 (1995); Stuart B. Rosenblum et al., Abstract, *Discovery of SCH 58235: A Potent Orally Active Inhibitor of Cholesterol Absorption*, Baylor College of Medicine XII International Symposium on Drugs Affecting Lipid Metabolism (Nov. 7-10, 1995); Duane A. Burnett et al., *2-Azetidinones as Inhibitors of Cholesterol Absorption*, 37 J. Med. Chem. 1733 (1994).

[13] All of the patent applications and communications with the PTO described in this Complaint were by Schering Corporation and its agents, unless otherwise noted.

Figure 3. The Azetidinone Patents



*All expiration dates are calculated without pediatric exclusivity extensions.

(1) **1993-1994: Merck files two patent applications addressing hydroxyl-substituted azetidinone compounds useful as hypocholesteremic agents**

76. On September 21, 1993, Merck filed U.S. Patent Application 102,440, titled "Hydroxy-Substituted Azetidinone Compounds Useful As Hypocholesterolemic Agents." Merck abandoned the application.

77. On June 9, 1994, Merck filed U.S. Patent Application 257,593 as a continuation-in-part of the abandoned '440 application.

78. Both the '440 application and the '593 application disclosed that the inventions described were useful as hypocholesterolemic agents in the treatment and prevention of atherosclerosis. These applications explained that the liver is the major organ responsible for cholesterol biosynthesis and is the prime determinant of plasma cholesterol levels. When intestinal cholesterol absorption is reduced, less cholesterol is delivered to the liver, which makes less hepatic lipoprotein and clears more plasma cholesterol (mostly LDL). As Merck put it, "the net effect of inhibiting intestinal cholesterol absorption is a decrease in plasma cholesterol levels."

79. Merck went on to prosecute the '593 application for approximately three years.

(2) **1994-1996: Merck files a third and fourth patent application addressing hydroxyl-substituted azetidinone compounds**

80. On September 14, 1994, Merck filed the PCT/US94/10099 application as a continuation-in-part of the '593 application. The PCT'099 application added two example compounds in the specification, 3L and 3M, as well as *in vivo* data for 3L, 3M, and 6A-1.

81. On March 18, 1996, the PCT'0099 application became U.S. Patent Application No. 617,751. The specification for the '751 application, as filed, was identical to the specification of the PCT'0099 application.

82. Merck went on to prosecute the '751 application for approximately two years.

(3) **1994-Early 1997: Merck obtains its first azetidinone patent, covering processes (the '365 patent)**

83. On May 20, 1997, the '593 application – Merck's second azetidinone patent application – issued as U.S. Patent No. 5,631,365. The '365 patent was the first-issued Merck azetidinone patent.

84. The named inventors of the '365 patent are Drs. Rosenblum, Dugar, Burnett, Clader, and McKittrick. All worked for Schering in New Jersey.

85. The '365 patent was originally assigned to Schering Corporation of Kenilworth, N.J. In 2012, Merck Sharp & Dohme became the assignee of the '365 patent by means of a conveyance from Schering Corporation.

86. The '365 patent states that "the present invention relates to hydroxyl-substituted azetidinones useful as hypocholesterolemic agents in the treatment and prevention of atherosclerosis . . . the invention also related to a process for preparing hydroxyl-substituted azetidinones." It observes that "[a] few azetidinones have been reported as being useful in lowering cholesterol and/or in inhibiting the formation of cholesterol-containing lesions in mammalian arterial walls," citing U.S. Patent No. 4,983,594; Ran, *Indian J. Chem.* (1990); European Patent Publication No. 264,231; European Patent No. 199,630; and European Patent Application No. 337,549.

87. The summary of the invention describes hypocholesterolemic compounds of formula I or a pharmaceutically acceptable salt of those compounds. It also states that the invention "relates to" all of the following:

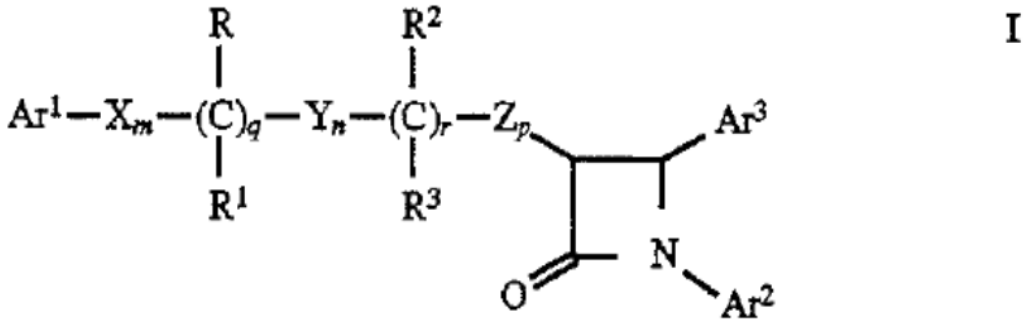
- "[A] method of lowering the serum cholesterol level in a mammal in need of such treatment comprising administering an effective amount of a compound of formula I,"

- "[A] pharmaceutical composition comprising a serum cholesterol lowering effective amount of a compounds of formula I in a pharmaceutically acceptable carrier;"

- "[T]he use of a hydroxyl-substituted azetidinone cholesterol absorption inhibitor of formula I for combined use with a cholesterol biosynthesis inhibitors [e.g., statins] … to treat or prevent atherosclerosis or to reduce plasma cholesterol levels;" and

- "[A] process for preparing certain compounds of formula I comprising [five specific steps]."

Figure 4. Hypocholesterolemic Compounds of Formula I



I

88. The specification confirms that the invention includes both enantiomers and racemic mixtures, and that one enantiomer may lead to greater cholesterol inhibition than another: "all isomers, including enantiomers . . . are contemplated as being part of this invention . . . including racemic mixtures." "Isomers can be prepared using conventional techniques, either by reacting chiral starting materials or by separating isomers of a compounds of formula I." "Those skilled in the art will appreciate that for some compounds of formula I, one isomer will show greater pharmacological activity than another isomer."

89. The specification notes that compounds of the invention can exist in "pharmaceutically acceptable" salt forms, identifies at least two dozen salt forms, and describes how to prepare salt forms.

90. The specification notes that "Compounds of formula I can be prepared by known methods, for example those described below and in WO93/02048," and then describes several methods of preparation. It then discloses that many, if not all, of the "starting compounds" used are "either commercially available or well known in the art and can be prepared via known methods."

91. The specification notes: "We have found that the compounds of this invention lower serum lipid levels, in particular serum cholesterol levels. Compounds of this invention have been found to inhibit the intestinal absorption of cholesterol and to significantly reduce the formation of liver cholesteryl (sic) esters in animal models. Thus, compounds of this invention are hypocholesterolemic agents by virtue of their ability to inhibit the intestinal absorption and/or esterification of cholesterol; they are, therefore, useful in the treatment and prevention of atherosclerosis in mammals; in particular in humans." It goes on to describe the procedure used to determine the in vivo activity of the compounds of formula I, using the "Hyperlipidemic Hamster."

92. The '365 patent has four claims. All four claim a process of preparing a compound of formula I. Claims 1 and 3 are independent claims; claims 2 and 4 depend on claims 1 and 3, respectively.

93. The '365 patent expired on May 20, 2014.

(4) Late 1997: Merck files a fifth patent application addressing azetidinones, addressing combination use with statins

94. On October 14, 1997, Merck filed U.S. Patent Application 953,825 – titled "combinations of hydroxyl-substituted azetidinone compounds and HMG CoA reductase inhibitors" – as a continuation-in-part of the '751 application.

(5) **Mid-1998: Merck obtains a second azetidinone patent covering compounds, a composition, and a method of treating atherosclerosis (the '115 patent)**

95. On June 16, 1998, the '751 application issued as U.S. Patent No. 5,767,115. The '115 patent had nine claims. Claims 1-7 claim compounds, claim 8 claims a pharmaceutical composition for the treatment or prevention of atherosclerosis (or for the reduction of plasma cholesterol levels), and claim 9 covers a method of treating or preventing atherosclerosis (or reducing plasma cholesterol levels) comprising administering to a mammal in need of such treatment an effective amount of a compound of claim 1.

96. Ezetimibe is within the scope of claims 1-3, 5, and 7 of the '115 patent. Ezetimibe is designated "6A" and is described in Example 6 at column 31, lines 1-10 of the specification and in claim 7 at column 40, lines 19-21.

97. According to Merck, the '115 patent expired on June 16, 2015.

(6) **Late 1998: Merck obtains a third azetidinone patent for use in combination with statins (the '966 patent)**

98. On December 9, 1998, the '825 application issued as U.S. Patent No. 5,846,966.

99. All claims in the '966 patent refer to a hydroxyl-substituted azetidinone used in combination with an HMG CoA reductase inhibitor – i.e., a statin. Claim 1 refers to hydroxylsubstituted azetidinone compounds used in combination, claims 2-5 refer to compositions of those compounds used in combination, and claim 6 refers to methods of treating or preventing atherosclerosis or reducing plasma cholesterol levels in combination with statins. Claim 8 explicitly refers to simvastatin and atorvastatin.

C. 2000: Merck asks the PTO to reissue the '115 patent with new ezetimibe claims

100. In early 2000, Merck – including Schering Corporation – was preparing an NDA for the drug product that came to be known as Zetia. Merck closely reviewed its existing patent portfolio, knowing, as all sophisticated pharmaceutical manufacturers do, that the FDA would require it to identify the patents that claim the Zetia product (or a method of using it) by listing them in the Orange Book.

101. On June 15, 2000, Merck filed Reissue Application No. 09/594,996, asking the PTO to reissue the '115 patent. In preliminary remarks, Merck stated that the reissue application was filed "to correct an error concerning the failure to appreciate the full scope of the invention by not including claims of narrower scope directed to one of the most preferred compounds disclosed in the specification," namely, ezetimibe (described as 1-(4-fluoro[phenyl)-3(R)-[3(S)-(4 fluorophenyl)-3-hydroxypropyl)]-4(S)-(4-hydroxyphenyl)-2-azetidinone). Merck proposed adding claims 10-13, claiming the ezetimibe compound (in both prose and graphic form, claims 10 and 11), a pharmaceutical composition for the treatment or prevention of atherosclerosis or the reduction of plasma cholesterol levels (claim 12), a method of treating or preventing atherosclerosis or reducing plasma cholesterol levels (claim 13), and a method of use thereof.

102. Merck submitted a declaration in support of reissue signed by James R. Nelson, Staff Vice President and Associate General Counsel, Patents & Trademarks at Schering-Plough Corporation and Vice President at Schering Corporation. Nelson described the error as "the failure to include a specific claim to one of the most preferred compounds."

D. 2001-2002: Merck obtains approval for Zetia, the RE'721 patent, and a corresponding 16-month patent term extension

(1) 2001: Merck files an NDA for Zetia

103. On December 27, 2001, while the application for reissue was pending, Merck submitted NDA 21445, seeking FDA approval to market ezetimibe tablets in the United States under the brand name Zetia for the treatment of hypercholesterolemia.

104. The NDA sponsor is sometimes identified as Merck/Schering-Plough Pharmaceuticals and sometimes identified as MSP Singapore Company LLC. The proposed labeling submitted with the NDA is marked "COPYRIGHT Merck/Schering-Plough Pharmaceuticals." In correspondence, Schering Corporation is identified as the U.S. agent for MSP Singapore. During its review, the FDA corresponded with Schering's Regulatory Affairs department, including with Joseph F. Lamendola, Jack Scannelli, and Beth DiDomenico.

105. The FDA's review of Zetia took approximately ten months. As discussed below, Merck later sought and obtained a patent term extension for the period of time encompassed by this regulatory review.

(2) May 2002: The PTO reissues the '115 patent as the RE'721 patent

106. On May 28, 2002, the RE'966 application issued as U.S. Patent No. RE37,721 with new claims 10-13. These included the compound ezetimibe (claims 10-11), a composition of ezetimibe (claim 12), and a method of using ezetimibe to treat or prevent atherosclerosis or reduce plasma cholesterol levels (claims 13).

(3) October 2002: The FDA approves Zetia

107. On October 25, 2002, the FDA approved the Zetia NDA and granted it a five-year New Chemical Entity ("NCE") exclusivity. Merck launched Zetia later that month. Zetia

quickly became a steady source of profits for Merck, with annual U.S. sales of approximately $1 billion in 2010 and $1.6 billion by 2016.

108. The originally-approved labeling reflects that Zetia is manufactured for Merck/Schering-Plough Pharmaceuticals by Schering Corporation *or* Merck & Co., Inc.

(4) December 2002: Merck seeks a 16-month extension for the RE'721 patent

109. On December 12, 2002, Merck – via James R. Nelson of Schering – requested an extension of the patent term of the RE'721 patent based on the duration of the FDA's review of the Zetia NDA, pursuant to 35 U.S.C. § 156 and 37 C.F.R. §§ 1.710-1.791. Merck asked that 497 days be added to the term of the patent. Ultimately, on January 17, 2006, the RE'721 patent was extended through October 25, 2016. The PTO (in reliance on information obtained from Schering and confirmed by the FDA) determined that the RE'721 patent was eligible for a patent term extension of 497 days. The PTO noted that the period of FDA review was 948 days, but noted that 35 U.S.C. § 156(c)(3) operates to limit the term of the extension: "the term of the patent measured from the date of approval of the approved product plus any patent term extension cannot exceed fourteen years." With the extension, the RE'721 patent was set to expire on October 25, 2016 (fourteen years from the date of FDA approval).

E. <u>The launch of Vytorin</u>

110. By 2004, Merck knew that Zocor would lose patent protection and face generic competition in either 2005 or 2006. Merck estimated that Zocor sales would drop from more than $4 billion annually to less than 25% of that. In 2004, Merck also had to withdraw its blockbuster arthritis drug, Vioxx, from the market. To soften the impact of these actual and impending losses, Merck worked with Schering to package patent-protected Zetia with Zocor

as a new patented drug, Vytorin.[14] The FDA approved Vytorin in July 2004 based on its ability to lower LDL cholesterol levels by up to 20% over use of Zocor alone. By incorporating Zocor into Vytorin, Merck positioned itself to execute a strategy to switch purchasers from Zocor to Vytorin, which would help preserve profits when Zocor went off patent in 2006. Merck said it planned to persuade doctors to switch patients to Vytorin before 2006, when generic competition starts in the United States for Zocor, the company's biggest drug.[15]

111. Merck viewed Vytorin as a critical product in its portfolio and, along with Zetia, the second piece of a cholesterol "franchise." Speaking at an investor conference in January 2006, Merck's then CEO Richard Clark said Zetia and Vytorin were "critical to our future." In promoting Zetia and Vytorin, Clark also promoted the positioning of those products with "managed care." In 2006, Vytorin sales exceeded $2 billion globally. These profits bolstered Merck's stock price.[16]

F. April 2006: Merck obtains its first "sterol non-absorption" patent (the '106 patent)

112. After Merck filed its NDA, but before it was approved, Merck sought to extend its patent protection for Zetia. Merck filed a series of patent applications relating to compounds that inhibit sterol absorption and methods for treating specific conditions with those compounds.

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[14] *See* Andrew Pollack, *Two Drug Makers Pin Hopes on a Cholesterol Remedy*, New York Times (July 22, 2004) ("A successful introduction of Vytorin is crucial for Merck to retain its standing in the market for cholesterol drugs, probably the industry's single biggest category."), available at https://www.nytimes.com/2004/07/22/business/two-drug-makers-pin-hopes-on-a-cholesterol-remedy.html.

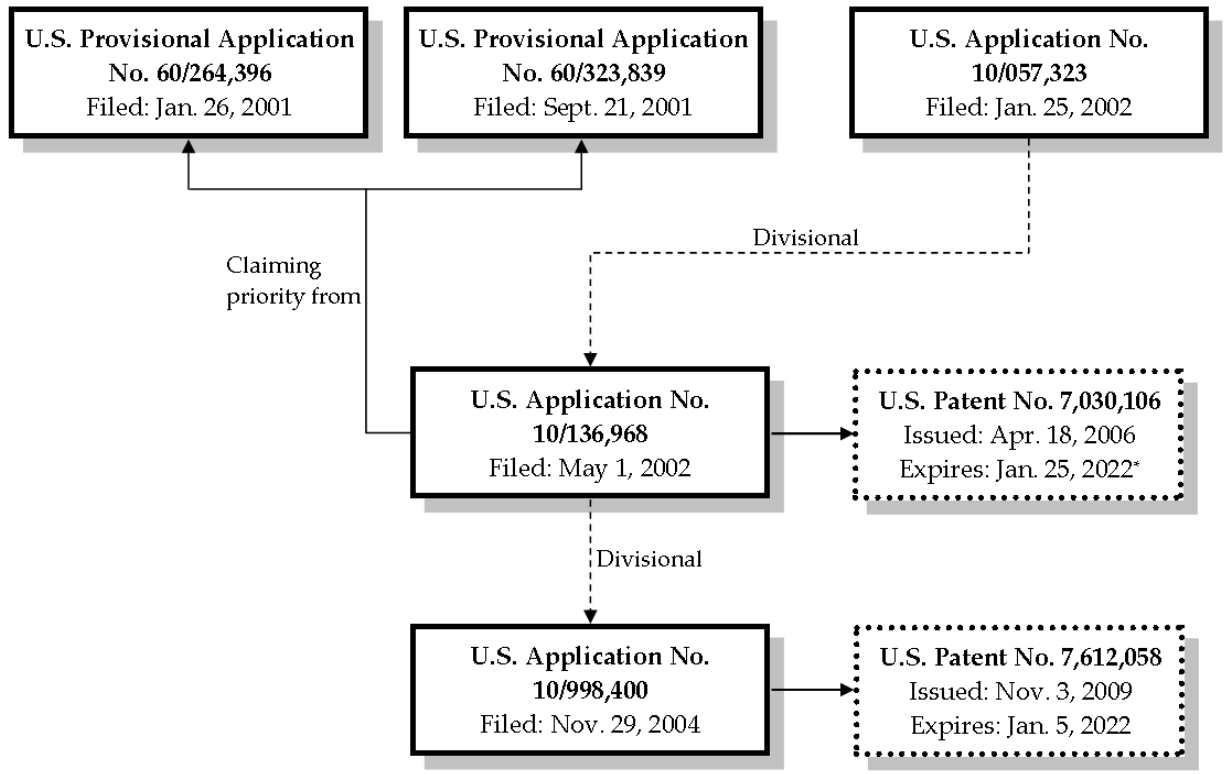
[15] *Id.*

[16] In 2008, it was revealed that Congress was investigating allegations that Merck concealed a study that failed to demonstrate advantages of Zetia and Vytorin. Later studies confirmed the clinical benefits of Zetia as a complement to statins.

Two issued as patents (the '106 patent and the '058 patent). For shorthand, this family of patents is referred to as "the sterol non-absorption" applications and patents.

113. The sterol non-absorption applications did not claim priority to, or derive from, the azetidinone applications. Nor did the two sets of applications share any inventors.

Figure 5. The Sterol Non-Absorption Patents



*All expiration dates are calculated without pediatric exclusivity extensions.

114. On April 18, 2006, Merck's Application No. 10/136,968[17] issued as U.S. Patent No. 7,030,106. The '106 patent was Merck's first sterol non-absorption patent. It has two

[17] On January 25, 2002, Merck filed Utility Application No. 10/057,323. The '323 application claimed priority to two provisional applications, filed in January 26, 2001 and September 21, 2001, respectively. It did not claim priority to, nor was it related to, the azetidinone patents described above. On May 1, 2002, Merck filed Application No. 10/136,968 as a divisional of the '323 application. The primary examiner was San-Ming Hui. The '323 and '968 applications purported to address compounds and compositions that inhibited sterol absorption.

claims. The inventor is listed as Wing-Kee Philip Cho of Princeton, NJ. The assignee was originally Schering Corporation.

115. According to Merck, the '106 patent originally was set to expire on January 25, 2022 but, with a pediatric extension, is now set to expire on July 25, 2022.

116. The '106 patent specification says that "the present invention relates to therapeutic combinations of peroxisome proliferator-activated receptor (PPAR) activator(s) ***and*** sterol absorption inhibitor(s) for treating vascular conditions (including atherosclerosis)" (emphasis added).

117. The '106 patent claims pharmaceutical compositions of ezetimibe that were earlier disclosed in the RE'721 patent.[18] Given this and other earlier disclosures, the '106 patent is, and clearly was at the time of its issuance, invalid as obvious and/or for obviousness-type double patenting.

118. By this time, Merck had listed in the Orange Book the RE'721 azetidinone patent, the '966 combination-with-statins patent, and the '106 sterol non-absorption patent. The '365 process patent was not listed in the Orange Book, likely because process patents – unlike product or method of use patents – are not eligible for listing.

[18] The compound represented in Formula II of claims 1 and 2 of the '106 patent is ezetimibe. The table in claims 1 and 2 describing the composition lists lactose monohydrate (a sugar); microcrystalline cellulose (a starch); povidone (a disintegrant); crosscarmellose sodium (a dissolving agent); sodium lauryl sulfate (a foaming agent); and magnesium stearate (a release agent). All are conventional excipients and additives. The RE'721 specification explicitly refers to compositions made using conventional excipients and additives and conventional techniques, including "non-toxic compatible fillers, binders, disintegrants, buffers, preservatives, antioxidants, lubricants, flavorings, thickeners, coloring agents, emulsifiers and the like."

G. October 2006: Glenmark files the first ANDA for generic Zetia.

119. On or about October 25, 2006, generic drug manufacturer Glenmark filed ANDA 78-560, seeking FDA approval to market an AB-rated generic version of Zetia. That day was the first day on which applicants to market generic versions of Zetia were permitted to file an ANDA for that product – one year before expiration of Merck's five-year NCE exclusivity – and then only if the ANDA included a Paragraph IV certification.

120. Merck's new chemical entity exclusivity expired on October 25, 2007, one year after the date Glenmark filed its ANDA. Glenmark could not come to market until after that exclusivity expired.

121. Glenmark's ANDA included a Paragraph IV certification to all of the patents then listed in the Orange Book: the RE'721 azetidinone patent, the '966 combination-with-statins patent, and the '106 sterol non-absorption patent. Because the '365 process patent was not listed in the Orange Book, Glenmark did not need to certify to it in its ANDA.

H. 2007-2008: Merck sues first-filer Glenmark; Glenmark asserts counterclaims

(1) Early 2007: Merck sues Glenmark for infringing the RE'721 patent only

122. On or about February 9, 2007, Glenmark notified Merck of its ANDA filing and provided a detailed account of why the patents were invalid, unenforceable, and not infringed by Glenmark's ANDA product ("Glenmark's paragraph IV letter").

123. On March 22, 2007, Merck[19] sued Glenmark in the District of New Jersey. Merck alleged that Glenmark's ANDA infringed the RE'721 patent.

[19] In this litigation, plaintiffs Schering Corporation and MSP Singapore Company LLC referred to themselves collectively as "Schering." Plaintiffs refer to them here as "Merck" instead.

124. Merck did not sue Glenmark, in this suit or any other, for infringing either of the two other Orange-Book-listed patents, the '966 and '106 patents. Merck apparently did not believe that it could realistically expect to win a lawsuit asserting that Glenmark's generic ezetimibe product would infringe the '966 combination-with-statins azetidinone patent or the '106 sterol nonabsorption patent because those patents were inapplicable, invalid, or not infringed. Glenmark's product did not include a statin. The unasserted '106 patent was, and is, invalid as obvious (as described above).

125. Under Hatch-Waxman, Merck's filing of the RE'721 lawsuit – irrespective of its prospects of success – triggered a 30-month stay, running from the date Glenmark notified Merck of its Paragraph IV letter. This stay prevented the FDA from granting final approval of Glenmark's ANDA until the earlier of (i) the expiration of the thirty-month stay, or (ii) entry of a final judgment that the RE'721 patent was invalid, unenforceable, and/or not infringed.[20]

126. Glenmark represented in a pleading early on that "[t]he amount at issue in this case is at least $1 billion, representing the anticipated sales by Glenmark of its generic product (and the corresponding loss of sales by [Merck])."

(2) Spring 2007: Glenmark counterclaims, alleging the RE'721 patent is invalid and unenforceable

127. On May 23, 2007, Glenmark answered, listed its affirmative defenses, and asserted counterclaims.[21] Glenmark sought a declaratory judgment that the RE'721 patent was

[20] Thirty months from the date Glenmark sent its paragraph IV certification is August 9, 2009. At one point during the litigation, Merck asserted that the 30-month stay expired on October 25, 2010. Plaintiffs allege here that generics would have entered as early as December 6, 2011, so the day on which the stay expired – under either interpretation – is before alleged generic entry.

[21] Glenmark filed a corrected answer on June 7, 2007. On March 10, 2008, Glenmark filed a first amended answer and counterclaim.

invalid and/or unenforceable. Glenmark asserted that the RE'721 patent was invalid for double patenting, anticipation, obviousness, lack of enablement, and inventorship issues. Glenmark also asserted that the RE'721 patent was unenforceable due to inequitable conduct and that Merck was estopped or precluded from asserting infringement by reasons of actions taken and statements made to the PTO during prosecution of the application(s) that led to the RE'721 patent.[22] Glenmark refined these arguments as the litigation progressed.

128. *Invalid for inherent anticipation.* Glenmark argued that at least two compounds claimed in the RE'721 patent are inherent metabolites of a hypercholesterolemic compound (SCH48461) disclosed in an earlier Schering patent application. Merck had disclosed two compounds claimed in the RE'721 patent in an earlier patent application: International Application No. PCT/US92/05972, filed on July 21, 1992 and published on February 4, 1993 as WO 93/02048 (the "PCT'048 publication").[23] Upon ingestion, at least one of these earlier disclosed compounds, SCH48461 (disclosed as Example 9), is metabolized to form two hydroxyl-substituted compounds that are both claimed in the RE'721 patent. These metabolites inherently anticipate the claims of the RE'721 patent.

[22] In Glenmark's first amended answer and counterclaim, filed on March 10, 2008, it added a claim asserting that the 497-day patent term extension Merck received for the RE'721 patent was invalid.

[23] The named co-inventors of PCT'048 are Duane A. Burnett, John W. Clader, Tiruvettipuram K. Thiruvengadem, Chou-Hong Tann, and Junning Lee. Burnett and Clader are named as co-inventors of the '721 patent. The publication date of the PCT'048 predates all applications to which the RE'721 claims priority.

129. Under the doctrine of inherent anticipation, "a prior art reference may anticipate without disclosing a feature of the claimed invention if that missing characteristic is necessarily present, or inherent, in the single anticipating reference."[24]

130. Merck and Schering were well aware of the doctrine of inherent anticipation. That doctrine featured prominently in a case Schering brought against Geneva Pharmaceuticals for allegedly infringing a patent for the prescription drug Claritin. There, on August 8, 2002, the district court concluded that "the natural, inevitable production of metabolic DCL upon human ingestion of loratadine, although not fully appreciated by persons of ordinary skill in that field until more recently . . . , demonstrates that this process is an inherent characteristic or functioning of the use of loratadine, the subject of the '233 patent. Therefore, that patent inherently anticipates Claims 1 and 3 of the '716 patent, rendering them invalid." The district court observed that "this is not a new doctrine," and cited cases from the 1980s and '90s. The district court also noted that Schering's policy arguments to the contrary were "not persuasive" and that the Patent and Trademark Appeals Board's opinions Schering cited in support of its arguments that inherency by anticipation did not apply were "not consistent with the Federal Circuit law." The Federal Circuit later affirmed.

131. *Inequitable conduct for failure to disclose inherency.* Glenmark argued that Merck committed inequitable conduct during prosecution of the RE'721 patent by not disclosing the inherency of these metabolites to the PTO. Merck did not do so before the RE'721 patent issued, nor did it do so in any post-issuance communications with the PTO about

[24] *Schering Corp. v. Geneva Pharm., Inc*., 339 F.3d 1373, 1377 (Fed. Cir. 2003) (citing *Cont'l Can Co. v. Monsanto Co*., 948 F.2d 1264, 1268 (Fed. Cir. 1991)), *reh'g denied*, 348 F.3d 992 (2003).

the RE'721 patent.[25] A finding of inequitable conduct renders the entire patent-in-suit unenforceable.

132. Glenmark identified several publications describing the work that the Merck scientists did to investigate compound SCH48461, its metabolites and metabolite-like analogues, that supported its inherency argument – many authored or reviewed by Merck scientists who were also inventors of the RE'721. Merck never disclosed these publications to the PTO during prosecution of the RE'721 patent. Glenmark argued that these publications would have been material to the PTO when examining the RE'721 patent. That Merck withheld them, and key information they contained, reflects deceptive intent.[26] These publications included:

- Margaret Van Heek et al., Abstract, *Isolation and Identification of the Active Metabolite(s) of SCH48461 and Possible* in Vivo *Mechanism of Action for their Inhibition of Cholesterol Absorption*, Baylor College of Medicine XII International Symposium on Drugs Affecting Lipid Metabolism (Nov. 7-10, 1995) (the "Van Heek 1995 abstract");

- Harry R. Davis, Jr. et al., Abstract, *The Hypocholesterolemic Activity of the Potent Cholesterol Absorption Inhibitor SCH 58235 Alone and in Combination with HMG CoA*

[25] The RE'721 patent issued on May 28, 2002. The district court *Schering v. Geneva* opinion issued on August 2, 2002. On August 14, 2002, Schering filed a Request for Certificate of Correction for the RE'721 patent with the PTO, seeking to correct the priority information recited in the RE'721 patent (likely to ensure that it was treated as an application filed under 35 U.S.C. § 371 and therefore had a later expiration date than the '365 and '966 patents). On December 12, 2002, Schering filed a Request for Patent Term Extension with the PTO. On August 1, 2003, the Federal Circuit affirmed the district court's inherency decision. Schering's request for patent term extension was not resolved until August 29, 2006. Between May 28, 2002 and the conclusion of the patent term extension in 2006, Schering never mentioned inherency or either *Schering v. Geneva* decision in any of its communications with the PTO about the RE'721 patent.

[26] Rather than repeat the details of Glenmark's discussion of these publications here, Plaintiffs incorporate by reference ¶¶ 30-171 of Glenmark's First Amended Answer and Counterclaims, *Schering Corp. v. Glenmark Pharm., Inc., USA*, No. 07-cv-01334 (D.N.J. Mar. 10, 2008), ECF No. 54.

Reductase Inhibitors, Baylor College of Medicine XII International Symposium on Drugs Affecting Lipid Metabolism (Nov. 7-10, 1995) (the "Davis 1995 abstract");

- Stuart B. Rosenblum et al., Abstract, *Discovery of SCH 58235: A Potent Orally Active Inhibitor of Cholesterol Absorption*, Baylor College of Medicine XII International Symposium on Drugs Affecting Lipid Metabolism (Nov. 7-10, 1995) (the "Rosenblum 1995 abstract");

- John W. Clader et al., *2-Azetidinone Cholesterol Absorption Inhibitors: Structure-Activity Relationships on the Heterocyclic Nucleus*, 39 J. Med. Chem. 3684 (1996) (the "Clader 1996 publication");

- Sundeep Dugar et al., *Metabolism and Structure Activity Data Based Drug Design: Discovery of (-) SCH 53079, an Analog of the Potent Cholesterol Absorption Inhibitor (-) SCH 48461*, 11 Bioorganic & Med. Chem. Letters 1271 (1996) (the "Dugar 1996 publication");

- Margaret Van Heek et al., *In Vivo Metabolism-Based Discovery of a Potent Cholesterol Absorption Inhibitor, SCH58235, in the Rat and Rhesus Monkey through the Identification of the Active Metabolites of SCH 48461*, 283 J. Pharmacology & Experimental Therapeutics 157 (1997) (the "Van Heek 1997 publication");

- Stuart B. Rosenblum et al., *Discovery of 1-(4-Fluorophenyl)-(3R)-[3-(4-fluorophenyl)-(3S)-hydroxypropyl]-(4S)-(4-hydroxyphenyl)-2-azetidinone (SCH58235): A Designed, Potent, Orally Active Inhibitor of Cholesterol Absorption*, 41 J. Med. Chem. 973 (1998) (the "Rosenblum 1998 publication").[27]

133. *Inequitable conduct re patent term extension.* Glenmark argued that Merck further committed inequitable conduct when seeking the RE'721 patent term extension, by not disclosing that at least some claims were invalid due to inherent anticipation. Merck sought to extend the term of the RE'721 patent claims after *Schering v. Geneva* was decided, knowing that claims it sought to extend were invalid under the doctrine of inherent anticipation.

134. *Invalidity for lack of enablement.* Glenmark argued that the RE'721 patent does not teach one skilled in the art how to use ezetimibe to prevent atherosclerosis without further experimentation, which renders claims invalid for lack of enablement.

[27] Submitted October 16, 1997.

135. To be enabled, the specification of the patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. Articles published after a patent application's filing date can establish a lack of enablement.

136. *Failure to name inventors.* Glenmark argued that Merck may have failed to name all inventors, and took discovery on the issue. On May 10, 2006, the industry group Pharmaceutical Research and Manufacturers of America ("PhRMA") presented the Discoverers Award for contributions to the discovery of ezetimibe to three individuals: Harry R. Davis, Jr., Dr. Margaret Van Heek, and Kevin B. Alton. Merck had nominated all three. None were listed as inventors on the RE'721 patent.

137. *Lack of proper reissue.* Glenmark argued that reissue was improper, and thus the reissued claims were invalid, for failure to identify an error in the '115 patent of the type that may be properly corrected through reissue.

138. *Invalidity for obviousness-type double patenting.* Glenmark argued that the subject matter claimed in the RE'721 patent was not patentably distinct from matter claimed in Merck's earlier-issued (and earlier-expiring) '365 patent. As a result, at least some claims of the RE'721 patent were alleged to be invalid for obviousness-type double patenting.

I. Spring 2009: Glenmark receives tentative approval, and Merck receives new regulatory exclusivities

139. On April 24, 2009, the FDA gave tentative approval to Glenmark's Zetia ANDA. It did so within the 30 months allotted by statute, which secured Glenmark's first-filer status for 180-day exclusivity.

140. At the time Glenmark received tentative approval, the 30-month stay prevented Glenmark from launching its generic.

141. In 2009, the FDA listed a new exclusivity in the Orange Book – for adding pediatric information to the label – which expired on June 5, 2011. The FDA also added pediatric exclusivities to all listed patents and exclusivities, which expired on December 6, 2011.

J. Summer 2009: Glenmark seeks partial summary judgment on two discrete legal issues.

142. In separate motions for partial summary judgment filed in July of 2009, Glenmark raised two discrete legal issues as to which it did not believe there were any disputed issues of fact that prevented entry of final judgment in its favor. At that time, trial was scheduled for May of 2010.

143. In the first motion, Glenmark argued that the RE'721 patent was invalid for Merck's failure to identify an error of the type that may be properly corrected in reissue under 35 U.S.C. § 251.

144. In the second motion, Glenmark argued that 12 of the 13 claims in the RE'721 patent were invalid by reason of obviousness-type double patenting, in light of Merck's earlier-issued '365 patent.

145. In August 2009, counsel for Glenmark and Schering had begun discussing the possibility of settling the patent litigation. Even at that early juncture in negotiations, the parties understood that if Glenmark succeeded in challenging the RE'721 patent, that would have ruinous effects on the profitability of both Zetia and Vytorin. For example, according to an email drafted by Glenmark's lead negotiator, Vijay Soni, he spoke with Schering's general

counsel, Henary Hadad and "reminded" Hadad of the fact that a court decision in favor of Glenmark "will impact Vytorin product, which SP [Schering Plough] did realize . . ."[28]

K. Fall 2009: Merck obtains the second sterol absorption patent (the '058 patent)

146. On November 3, 2009, while the Glenmark summary judgment motions were pending, Merck's Application No. 10/998,400[29] issued as U.S. Patent No. 7,612,058, Merck's second sterol non-absorption patent.

147. The '058 patent is subject to a terminal disclaimer. According to Merck, it originally was set to expire on January 25, 2022, and with a pediatric extension is set to expire on July 25, 2022.

148. The '058 patent includes 10 claims. All cover methods of treating conditions associated with high cholesterol (*e.g.*, atherosclerosis, diabetes, obesity) comprising administering a pharmaceutical composition consisting of the same compound and routine pharmaceutical additives described in the '106 patent (Formula II, ezetimibe). The '058 patent was at the time it was issued, and at all times thereafter, invalid for the same reasons as the '106 sterol non-absorption patent. Like the '106 patent, the named inventor is Philip Wing-Kee Cho.

L. Spring 2010: Par becomes Glenmark's partner in generic Zetia

149. On April 30, 2010, Glenmark and Par entered into a Marketing and Distribution Agreement (the "Glenmark/Par Distribution Agreement") whereby Glenmark appointed Par to act as its exclusive distributor to market, distribute, and sell Glenmark's generic Zetia in the

[28] Exhibit 10 to Glenmark's Motion for Summary Judgment on All Claims, ECF No. 1039-10 (GLENMARK-ZETIA-00281992) (publicly filed).

[29] On November 29, 2004, Schering filed Application No. 10/998,400 as a divisional of the '968 application, seeking another inhibition of sterol absorption patent. The primary examiner was again San-Ming Hui.

United States. In exchange for, among other things, an upfront payment to Glenmark and an agreement to share net profits, Glenmark granted Par the exclusive right to distribute its generic Zetia in the United States.

150. The Glenmark/Par Distribution Agreement states that Glenmark provided Par "all documents or materials in its possession or control" relating to the ANDA litigation between Merck and Glenmark. The Agreement required Par and Glenmark to "jointly" make "all material decisions" in the Merck-Glenmark patent infringement litigation or any other litigation involving generic Zetia. Specifically, section 9.2.2 of the Glenmark/Par Distribution Agreement, entitled "Decisions," provided:

> 9.2.2 Decisions. Glenmark shall keep Par reasonably informed regarding material developments with respect to any Litigation. Glenmark shall continue to control the defense of the Litigation, except that all material decisions with respect to the Litigation shall be made jointly by Glenmark and Par; provided, however, that if the Parties fail to promptly agree upon a course of action, Glenmark's decision shall control any Litigation as well as any settlements thereof. Glenmark and Par, to the extent necessary to protect and preserve the attorney-client privilege between Glenmark and its counsel, shall enter into a common interest and/or joint defense agreement.

151. Under the terms of the Glenmark/Par Distribution Agreement, Glenmark could not settle its lawsuit with Merck without Par's "written consent." And, if any such settlement were to occur, Glenmark was required to share any proceeds with Par. Pursuant to this provision, Par gave its written consent to the unlawful reverse payment agreement between Merck and Glenmark.

152. The Glenmark/Par Distribution Agreement also required Par to consult with Glenmark regarding marketing, pricing, and distribution decisions, and explicitly established a Steering Committee comprised of "an equal number of duly qualified representatives of Par

and Glenmark . . . with the necessary authority to deal with and make decisions concerning the matters within the Steering Committee's authority." The Steering Committee's responsibilities included:

a. "advise on the overall strategy for the marketing of the Product [generic Zetia]";

b. "review and advise on the marketing plan";

c. "monitor the activities and performance of Par related to the marketing plan";

d. "review and advise on decisions in connection with the marketing plan";

e. "review and advise on major amendments to the marketing plans, including without limitation, with respect to timelines and budgets";

f. "discuss pre-Launch marketing plans and strategies (including the estimated Launch Date)"; and

g. "review and advise on life cycle management plans for the Product [generic Zetia] after the Product has been launched or has been actively planned for Launch."

142. The Glenmark/Par Distribution Agreement required Glenmark and Par to establish the Steering Committee within 30 days of the Agreement's execution, and to meet a minimum of twice a year. It also provided that the Steering Committee would be chaired by a Glenmark representative prior to "pre-Launch commercialization planning" but thereafter by a representative of Par. Under the Agreement, Par became Glenmark's partner in the profits made from the sale of Glenmark's generic Zetia in the United States, as well as the Merck-Glenmark ANDA litigation, any settlement of that litigation, and any proceeds or benefits of such a settlement.

143. Par performed under the Glenmark/Par Distribution Agreement by consenting to the unlawful reverse-payment agreement between Merck and Glenmark, by distributing

Glenmark's generic Zetia in the United States, and by furthering the purposes of the unlawful conspiracy. Par benefited from the conspiracy because the profits it retained from the sale of Glenmark's generic Zetia were higher than they otherwise would have been as a result of the absence of competition from a Merck authorized generic.

M. Summer 2010: Merck and Glenmark/Par settle with a reverse payment

(1) The Court sends Glenmark's double-patenting argument to trial

153. On April 19, 2010, the Honorable Jose L. Linares of the U.S. District Court for the District of New Jersey issued opinions addressing Glenmark's motions for partial summary judgment. First, the court granted Glenmark's motion on invalidity, agreeing with Glenmark that reissuance of the '115 patent had been improper because Merck had failed to identify the kind of purported error that can be corrected in reissue. This functionally threw out claims 10-13, which were narrow claims covering ezetimibe only (often known as bullet claims). Merck moved for reconsideration of this order on April 30, 2010.

154. On the same day, the court denied Glenmark's second motion for partial summary judgment (obviousness-type double patenting), concluding that there were disputed issues of fact as to whether, at the time of the '365 patent, alternative processes for making the claimed azetidinone compounds existed that required resolution by trial.

(2) Two days before trial, Merck and Glenmark/Par agreed to settle in a deal that included a reverse payment from Merck to Glenmark/Par

155. Trial before Judge Linares was scheduled to begin on May 12, 2010. At issue were Glenmark's affirmative defenses and counterclaims, including its assertion that claims 1 through 9 were unenforceable because of Merck's intentional failure to disclose to the PTO either (1) that compounds claimed in the RE'721 were naturally occurring metabolites of

SCH46481 (and therefore inherently anticipated by earlier disclosures), or (2) the disqualifying prior art publications by Merck's own scientists that had been hidden from the PTO.

156. On May 10, 2010, two days before the scheduled start of trial, Merck and Glenmark entered into an agreement that settled the patent infringement lawsuit and unlawfully allocated the market for ezetimibe.

157. Merck and Glenmark agreed to the entry of a consent judgment. In order to ensure there were no adverse rulings concerning the RE'721 patent as a result of the litigation, a condition of the settlement included that the parties seek to have the court vacate its partial summary judgment decision invalidating claims 10-13 for improper reissue. The parties submitted a proposed order to the court, together with the consent judgment vacating the partial summary judgment order on claims 10-13. That proposed order makes reference to the fact that the ruling of the Board of Patent Appeals and Interferences in *Ex parte Tanaka*, on which the Court based its ruling invalidating claims 10-13, had been docketed for appeal.

158. The proceedings on entry of the consent judgment revealed that the parties had agreed that, subject to certain unrevealed caveats, Glenmark would not enter the market with its generic Zetia product until December 12, 2016.

159. As noted above, the Glenmark/Par Distribution Agreement prohibited Glenmark from settling with Merck absent Par's express written consent, which Par provided. The reverse payment agreement also identified Par as the distributor of the "Glenmark Product [generic Zetia] in the United States on or after the [unlawfully-delayed] Entry Date."

160. Par knowingly and voluntarily agreed to the terms of the unlawful settlement and authorized its execution by Glenmark. By operation of the Glenmark/Par Distribution Agreement, Par and Glenmark were partners in the distribution of Glenmark's generic Zetia;

both conspired with Merck to delay the entry of generic Zetia and to allocate the market for generic Zetia in the United States.

161. Although the consent judgment made reference to the settlement agreement, the agreement was not docketed in the court record, and the parties did not publicly reveal any of the remaining terms of that agreement at the time of the settlement. Nor have the full terms of that agreement been made public.

162. The no-AG agreement can be inferred from the following facts:

163. *First*, Merck previously admitted that marketing an authorized generic is often in its economic interest. For example, speaking about another blockbuster drug, Fosamax, a Merck executive acknowledged that Merck's "authorized generic strategy" will "maximize the value of the franchise" after entry by generic competitors.

164. *Second*, Merck had a well-established history of launching authorized generics in the face of generic competition. Other branded drugs for which Merck or Schering have launched authorized generic versions include Blocadren, Clinoril, Cozaar, Diprolene, Lotrisone, Nasonex, Singulair (Oral Granules), Temodar, Blocadren, K-Dur 10, K-Dur 20, and Lotrimin AF.

165. *Third*, Zetia was a blockbuster drug, with sales in the billions at the time a generic eventually launched in 2016. Absent Glenmark/Par's reciprocal agreement to delay entering the market, launching an authorized generic would have been in Merck's clear financial interest.

166. *Fourth*, when Glenmark/Par launched its generic on December 12, 2016, it issued a press release describing its generic Zetia as "the first and only generic version" of Zetia in the United States.

167. *Fifth*, when Glenmark/Par eventually did launch generic Zetia in late 2016, Merck did not launch an authorized generic during Glenmark/Par's 180-day ANDA-exclusivity period. The absence of a Merck authorized generic on the market in late 2016 and the first half of 2017 is strong evidence that Merck had made a contractual agreement with Glenmark/Par not to launch such a product. During this time period – the first six months of generic launch – Merck stood to earn millions of dollars from an AG launch.

168. *Sixth*, Glenmark reported to its shareholders in May 2017 that, before launching its generic product, it had expected to garner more than 58% of the combined brand and generic sales, which it in fact achieved within the first six months. In the absence of a no-AG pact, a typical generic pharmaceutical company would realistically expect to take a smaller share of the market (25-43%) due to competition from an AG.

169. Because Merck and Glenmark/Par kept the terms of their unlawful agreement confidential, the existence of the no-AG agreement could not have inferred until Glenmark/Par launched its generic in 2016 and Merck failed to launch a competing authorized generic product.

170. Certain terms of the reverse payment agreement have since become public. The reverse payment agreement confirms that, as a *quid pro quo* for Glenmark's agreement to drop its patent challenge and delay market entry for over five years, Merck promised not to launch a competing authorized generic version of Zetia during Glenmark/Par's eventual 180-day exclusivity period (the "no-AG agreement"). Under sections 5.2 and 5.4 of the reverse payment agreement, Glenmark/Par agreed not to launch generic Zetia until December 12, 2016 (or earlier under certain circumstances). Under section 5.3 of the unlawful reverse payment agreement, Merck agreed not to launch an authorized generic in competition with

Glenmark/Par "[d]uring any period of exclusivity to which Glenmark is entitled under 21 U.S.C. § 355(j)(5)(B)(iv) [180-day exclusivity], and through the expiration of [Merck's] rights under the '721 Patent and Ezetimibe Pediatric Exclusivity." As it turned out, Glenmark/Par was permitted to launch generic Zetia on December 12, 2016, Merck's rights under the '721 Patent (including pediatric exclusivity) expired on April 25, 2017, and Glenmark/Par's 180-day exclusivity expired on June 10, 2017.

171. Internal documents of Merck and Glenmark demonstrate that both companies understood the reverse payment agreement to prohibit Merck's launch of an AG for some period of time after Glenmark/Par's entry.

172. The no-AG agreement was a payment from Merck to Glenmark/Par worth substantially more than what Glenmark/Par could have earned if it prevailed in its patent litigation and come to market with generic Zetia in 2011 (or later) and faced an authorized generic competitor. Further, Glenmark/Par could not have obtained a no-AG agreement even had it won the patent infringement litigation. By delaying its generic entry for more than five years, and thereby obtaining a no-AG agreement from Merck, Glenmark/Par was ensured six months of exclusive generic sales, free from competition from Merck's authorized generic or any other generic competitors.

173. For Merck, the benefits of the no-AG agreement were enormous because it secured an additional six months of monopoly profits. The size of Merck's payment is strong evidence of Merck's belief that it would lose the patent litigation.

174. Absent the reverse payment agreement, generic entry would likely have occurred on or after December 6, 2011, when Merck's last regulatory exclusivity ended. By then, Glenmark/Par would have resolved the RE'721 infringement claims by either winning at trial,

settling on competitive terms (without a payment), or possibly launching at risk. Merck has never accused Glenmark/Par of infringing any other Orange Book-listed patents covering Zetia.

175. By December 6, 2011, other than the RE'721 patent (addressed below), no other impediments existed to the prompt approval and launch of generic Zetia.

176. *First*, Glenmark's ANDA had already received FDA tentative approval. In effect, Glenmark had met all preconditions for final FDA approval other than the 30-month stay triggered by Merck's enforcement of the RE'721 patent against Glenmark.

177. *Second*, no other patents held by Merck would forestall generic entry. The '966 patent had claims only to combination products, but generic Zetia is not a combination product, and Merck never enforced the '966 patent against Glenmark/Par. The '106 and '058 sterol nonabsorption patents were obvious in light of the RE'721 disclosures, and Merck never enforced those patents against Glenmark/Par. The '365 patent was limited to the narrow processes set out in that patent, and Merck never enforced the '365 patent against Glenmark/Par.

178. *Third*, Merck had no other exclusivity rights after December 5, 2011. Merck's NCE exclusivity expired in 2007. Two other exclusivities – an indication exclusivity I-493 and a pediatric exclusivity M-54 – were capable of being carved out of any generic label, and in any event had expired by December 5, 2011.

179. As to the RE'721 patent, in the absence of the reverse payment agreement and with Merck and Glenmark/Par acting as lawful, economically rational companies, generic entry would have occurred much sooner than it did. Such earlier entry would have occurred in one of three alternative ways.

180. *First*, absent the reverse payment agreement, Glenmark/Par and Merck could have settled their litigation, but without a reverse payment, with an earlier agreed entry date.

That agreed entry date would have been based on the merits of Merck's RE'721 infringement claims – claims that had no merit – and Merck's expected saved litigation costs rather than a payment. An arms-length settlement between economically rational, law-abiding companies would have led to an agreed entry date much earlier than December 2016.

181. *Second*, absent the reverse payment agreement, Glenmark/Par could have won the trial scheduled to start in May 2010. In that trial, a finder of fact would have concluded (for the reasons described above) that Merck failed to prove that Glenmark/Par infringed a valid patent for one or more of the following reasons:

- Merck (through the inventors, agents, and others with a Rule 56 duty) committed inequitable conduct by intentionally and deceptively hiding the fact that the RE'721 claimed compounds that were naturally occurring metabolites of SCH 48461 (and therefore inherently anticipated by its earlier disclosure in PCT'048), which would render the entire RE'721 patent invalid or unenforceable;

- Regardless of whether Merck committed inequitable conduct, the claims of the RE'721 patent were invalid for inherent anticipation; and

- The RE'721 patent was invalid for obviousness-type double patenting over the '365 patent.

182. Having gone to trial and won, Glenmark/Par would have launched generic Zetia soon after a district court ruling in its favor and the expiration of any other, lawful exclusivity.

183. *Third*, absent the reverse payment agreement, Glenmark/Par could have launched generic Zetia at risk, prior to a favorable district court decision, based on its internal views of the expected outcome of the patent trial.

184. Without Merck's reverse payment to Glenmark/Par, several additional generics would have come to market after Glenmark/Par's 180-day exclusivity ended – as early as June 6, 2011, and in any event much earlier than June 12, 2017.

185. In the absence of the unlawful agreement, Merck would have launched its authorized generic version of Zetia at or around the same time that Glenmark launched its generic.

(3) **The value of the agreement to Merck**

186. If a generic product had entered the market in December 2011, Merck would have lost at least 80% of its sales of branded Zetia. In addition, Merck would have lost a substantial portion of its sales of Vytorin as soon as purchasers could procure Zetia at generic prices. As explained in a January 2016 Forbes article regarding the eventual generic availability of Zetia:

> Anytime a drug becomes generic in the U.S., its price drops dramatically. It is likely that within 12 months, U.S. revenues for both Crestor and Zetia will drop by 90%. That's to be expected. However, the presence of generic forms for both drugs, rosuvastatin (Crestor) and ezetimibe (Zetia) will have other effects, both commercial and medical. Merck's Vytorin, a cholesterol lowering drug with sales of over a billion dollars, is actually a combination of ezetimibe and simvastatin (a generic statin originated by Merck's R&D group). By combining two complementary ways of lowering LDL-c in a single pill, Vytorin offers physicians a simple way of lowering LDL-cholesterol in their heart disease patients. But payers don't really care about convenience. They are focused on containing costs. Last year, a 30 day prescription of Zetia cost roughly $300, similar to the cost of 30 days of Vytorin. However, it is reasonable to expect that the cost of 30 days of the generic ezetimibe will be less than $10. Given that the 30 day cost of simvastatin, the other component of Vytorin, is even less than that, payers will reject prescription requests for Vytorin and require patients to take each drug individually. This will certainly be less convenient for both patients and physicians. But, by changing from $300 for a 30 day supply of Vytorin to perhaps as low as $10 for 30 days of both ezetimibe and simvastatin, payers will save millions of dollars.[30]

[30] John LaMattina, *Patent Expirations Of Crestor and Zetia And The Impact On Other Cholesterol Drugs*, Forbes (Jan. 18, 2016), available at https://tinyurl.com/yck7ybux.

187. By forestalling generic entry, Merck kept sales volumes and prices for Zetia and Vytorin at higher than competitive prices for as many as five years. As set forth above, the benefit to Merck of the reverse payment agreement was therefore in the billions of dollars.

(4) **The value of the agreement to Glenmark/Par**

188. But for the reverse payment agreement, Glenmark would have launched its generic product in 2011 (or at least well before it actually entered in 2016) in competition with Merck's authorized generic. Instead, as a result of the reverse payment agreement, Glenmark launched in 2016 in a market with no other generic competitors.

189. Discovery will reveal how Glenmark subjectively valued the benefits it obtained from the reverse payment agreement, but one can reasonably estimate the value to Glenmark by comparing the profits it would likely have earned but for the reverse payment agreement ("but-for profits") to the profits it actually earned in 2016.

190. To estimate Glenmark's "but-for" profits, one can apply certain well-grounded assumptions to publicly known facts.

191. *First*, to estimate what Merck would likely have earned had it entered the market in 2011, one can start from the fact that Merck earned approximately $1.298 billion in branded Zetia sales that year. Based on empirical data on generic entry, one can reasonably assume that (a) the generic products (including an authorized generic) would have captured 80% of Zetia sales by discounting generic prices by as much as 50% off the brand price and (b) Glenmark/Par would have captured half of all generic Zetia sales. This implies that Glenmark/Par would have generated sales of $129.8 million during the six-month exclusivity period in 2011.

192. *Second*, to estimate what Glenmark/Par actually earned in generic Zetia sales in 2016, one can start with the fact that branded Zetia prices increased by approximately 100%

(taking into account higher prices and higher sales volumes) between 2011 and 2016 (annual U.S. sales of $2.6 billion), (b) Glenmark charged approximately 80% of the branded price during the 180-day exclusivity period and (c) Glenmark/Par captured 100% of generic sales during the exclusivity period. Applying these assumptions, Glenmark/Par earned an estimated $832 million in 2016 during its period of exclusivity.[31] The value to Glenmark/Par of the reverse payment agreement was therefore in excess of $500 million at the time of the agreement.

N. 2010-2013: Merck seeks another reissue and sues more generics

(1) Summer 2010: Merck *admits* invalidity and seeks reissue of the RE'721 patent

193. On June 9, 2010, within a month after its settlement with Glenmark, Merck applied to the PTO for reissuance of the RE'721 patent. Again, to obtain reissue, the applicant must identify an error and attest, under oath, that the original patent is wholly or partly inoperative or invalid. Merck and its agents *admitted* that the RE'721 patent was invalid, citing inherent anticipation as the reason – just as Glenmark had argued.

194. In the required declaration accompanying its reissue application, Mark Russell, legal director of patents for Schering Corporation, attested to an error, and conceded that Glenmark's inherent anticipation argument was correct:

- "I have reviewed and understand the content of the above identified specification, including the claims . . . ."
- "I verily believe the original patent to be wholly or partly inoperative or invalid, for the reasons described below . . . by reason of the patentee claiming more than he had the right to claim in the patent."

[31] That number is calculated by dividing $2.6 billion in annual revenues in half for a six-month sales volume of $1.3 billion. We multiply that number by 80% to estimate the volume of generic sales ($1.04 billion million). We then multiply that number by 80% to account for lower generic prices.

- "At least one error upon which reissue is based is described as follows: At least one claim of RE37,721 E is potentially inherently anticipated by International published patent application WO 93/02048, filed July 21, 1992 (PCT/US92/05972) and published February 4, 1993 ("the '048 PCT publication"). See also European patent application EP 0524595 A1. In infringement litigation involving RE37,721 E, defendants have alleged that the PCT'048 publication recites, in Example 9, a compound, that when administered to mammals, as also reported in the PCT'048 publication, metabolizes into one or more compounds that fall within the scope of at least claims 1 of RE37,721 E."

- "I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this declaration is directed."

195. In Merck's preliminary remarks, attorneys Carl A. Morales and James F. Haley, Jr. of Ropes and Gray LLP, attorneys/agents for reissue applicants, made similar statements about inherent anticipation and invalidity being the basis for seeking reissue, and proposed amendments to the claims that ostensibly addressed these problems, namely cancelling claims 1-2 and 4-6 and amending claims 3 and 7-9.

(2) **Summer 2010: Merck sues Mylan and Teva for infringing the RE'721 patent; both counterclaim**

(a) The *Mylan* litigation

196. In or about April 2010, Mylan Pharmaceuticals, Inc. became the second company to file a Paragraph IV ANDA for generic Zetia.

197. Mylan sent its Paragraph IV notice for Zetia to Merck on May 25, 2010. On June 16, 2010, a week after it filed its latest reissue application, Merck sued Mylan for infringement of the RE'721 patent.[32]

198. Mylan counterclaimed, seeking declarations that both patents were invalid and unenforceable, and asserting claims for damages under the federal antitrust laws and state unjust enrichment laws. Mylan raised many of the arguments initially raised by Glenmark.

(b) The *Teva* litigation

199. On July 21, 2010, Teva Pharmaceuticals notified Merck that Teva had filed ANDA 78-724 for approval to make generic Zetia, including a Paragraph IV certification that the listed patents were invalid and unenforceable.

200. On September 1, 2010, Merck filed suit against Teva for infringement of the '966 and RE'721 patents in the District of New Jersey. Later that month, Merck formally agreed not to assert the '106 and '058 patents against Teva.

O. <u>Spring 2011: The Federal Circuit functionally overturns the *Glenmark* "error" summary judgment decision</u>

201. In April 2011, shortly before the '115 patent was reissued for a second time, the Court of Appeals for the Federal Circuit reversed the Board of Patent Appeals and Interferences' ruling in *Ex parte Tanaka*. In *Tanaka*, the Federal Circuit recognized "the narrow rule" permitting applicants to add "dependent claims as a hedge against possible

[32] Merck initially asserted that Mylan's Zetia product infringed the '966 patent, but withdrew that allegation part way through the litigation. Mylan had earlier filed an ANDA for Vytorin, a Merck product also marketed to combat high cholesterol that includes ezetimibe as one of two active ingredients. Merck's patent infringement suit against Mylan claiming infringement of the RE'721 and '966 patents by the Vytorin ANDA had been filed in December of 2009, and was pending before Judge Linares in the District of New Jersey at the time of the Merck-Glenmark settlement. The Vytorin and Zetia cases against Mylan were consolidated for all purposes in September 2010.

invalidity," noting that this rule "has been embraced as a reasonable interpretation of the reissue statute by this court and its predecessor for nearly fifty years."

202. While this decision effectively overturned the rationale behind the earlier *Glenmark* summary judgment about the technical requirements for invoking the reissue statute, it did not in any way undermine any of Glenmark's other arguments regarding invalidity or unenforceability of the RE'721.

(3) Summer 2011: Merck obtains reissuance of RE'721 patent (RE'461)

203. On June 14, 2011, the RE'721 patent was reissued as U.S. Patent No. RE42,461.

204. The RE'461 patent as reissued (or as re-reissued in this case) included only claims 8 through 13, and parts of claims 3 and 7, of the RE'721 patent.

(4) Summer 2011-2012: The *Mylan* and *Teva* litigations resolve

(a) July 2011: Merck and Teva settle

205. On July 7, 2011, before any substantive rulings in the case and while its parallel case against Mylan was pending, Merck settled with Teva. Judge Linares entered a consent judgment that prohibited Teva from launching generic Zetia before April 25, 2017. Teva conceded that the RE'461 patent was valid and would be infringed by its generic product. No other terms of the settlement were made public.

(b) August 2011: The Court denies Merck's motion for summary judgment of no inequitable conduct

206. On July 25, 2011, Merck filed an amended complaint against Mylan, substituting the newly reissued RE'461 patent for the RE'721 patent.

207. On August 19, 2011, Mylan filed an answer, affirmative defenses and counterclaims to Merck's amended complaint. In addition to alleging invalidity based on inherent anticipation and unenforceability based on failure to disclose prior art, Mylan also

alleged that the patents were unenforceable because of an intentional failure to disclose one of the inventors of ezetimibe.

208. On August 22, 2011, the court denied Merck's motion for summary judgment on Mylan's defense of inequitable conduct for failure to disclose prior art to the PTO, holding that "Mylan has put forth sufficient indirect and circumstantial evidence from which a reasonable fact finder could conclude that Schering had knowledge of the materiality of the withheld prior art," and that "a deliberate decision to withhold that information could . . . be reasonably inferred from the evidence already presented." The court also noted: "Schering does not appear to dispute that it had knowledge of the metabolite information during prosecution."

209. On the same day, Judge Linares granted in part Merck's motion for summary judgment against Mylan, ruling that Mylan's ANDA infringed claims 3, 10, 11, and 12

210. On September 30, 2011, Merck indicated that it would no longer be asserting any claims of the '966 patent against Mylan.

211. On November 18, 2011, Mylan sent a letter to the Court confirming that it would be withdrawing a defense, namely its claim "based on the non-disclosure of information demonstrating a relationship between compounds claimed in predecessor patents and metabolites of a prior art compound." This withdrawal "thereby reduc[ed] the issues to be tried before the Court on December 5, 2011." Mylan explained that this was done "in the interest of further streamlining the issues remaining for trial" and "having considered the time allotted by the Court for presentation of issues by the parties." Mylan also specifically clarified that it had "not withdrawn its additional defenses based on inequitable conduct, including those related to improper inventorship."

212. Mylan knew when it was deciding on its litigation strategy in fall 2011 that even

if it won the patent litigation, it would enjoy no regulatory or even *de facto* exclusivity. It knew that Zetia was a blockbuster drug, and that many other generic manufacturers had filed or would ultimately file ANDAs seeking to market generic Zetia. Mylan further knew that both of the previously announced Glenmark and Teva agreements may have included so-called "acceleration clauses" that would permit Glenmark and Teva to enter the market as soon as any other generic manufacturer – such as Mylan – entered. And it knew that, in order to trigger Glenmark's 180-day exclusivity, it would have to prevail in the patent case all the way through the Federal Circuit. Thus, regardless of the time and resources that Mylan poured into trying to win the patent litigation, the most it could hope to win would be (at best) a one-third or one-fourth share or (at worst) a one-seventh share of sales made at a price driven down to near marginal cost. Mylan's litigation strategy reflected the choice of not necessarily the best substantive defense, but the cheapest and fastest approach within practical constraints.[33]

(5) **2012: After a trial, the Mylan court found no inequitable conduct on inventorship (only)**

213. Judge Linares held a bench trial in December 2011, addressing only the claimed unenforceability of the RE'461 patent due to Merck's alleged inequitable conduct in misrepresenting the inventorship of the RE'461 patent. The trial did not address any allegations that the RE'461 patent was invalid as obvious over prior art, or any allegations of inequitable conduct based on Merck's failure to disclose invalidating prior art.

[33] Mylan was the first-filer with respect to another drug (Vytorin) involving the same patents at dispute in its Zetia litigation against Merck. But Mylan knew by Fall 2011 that: (1) it would not be entitled to 180-day exclusivity with respect to Vytorin because it would fail to get timely FDA tentative approval; and (2) other generic manufacturers would enter the market with generic Vytorin before or at the time that Mylan entered, even if it won the Vytorin patent case.

214. On April 27, 2012, the court ruled that Mylan had failed to prove inequitable conduct on the inventorship issue and therefore that the RE'461 patent was not invalid or unenforceable on that basis.[34]

215. Later, on August 7, 2013, Mylan's ANDA for Zetia received tentative approval from the FDA.

(6) 2012-2013: Schering sues Sandoz; Sandoz counterclaims; the parties settle

216. In August 2012, Sandoz notified Merck that Sandoz had filed ANDA 203-931 for approval to market generic Zetia.

217. On September 27, 2012, Merck sued Sandoz for infringement of the RE'461 patent in the District of New Jersey. In its amended complaint filed on May 29, 2013, Merck alleged that the purpose of Sandoz's ANDA submission was to obtain permission under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Sandoz's generic Zetia prior to the expiration of the RE'461, '966, '106, and '058 patents.

218. In its answer to the amended complaint, filed on July 26, 2013, Sandoz admitted that it had sought approval to manufacture and sell generic Zetia prior to the expiration of those patents, and further admitted that Sandoz intended to manufacture and sell generic Zetia "immediately and imminently upon approval of ANDA No. 203931 in light of potential third party exclusivity rights." Sandoz pleaded affirmative defenses including the unenforceability and invalidity of the RE'461 patent.

219. Sandoz also counterclaimed for a declaratory judgment of the unenforceability of the RE'721 and RE'461 patents, the invalidity and Sandoz's non-infringement of one or more of

[34] Mylan appealed the verdict, but on February 7, 2013 the Federal Circuit Court of Appeals affirmed.

the claims of those two patents as well as the '106 and '058 patents. Sandoz alleged, *inter alia*, that all the claims of the RE'721 and RE'461 patents were unenforceable due to inequitable conduct because Merck had "failed to disclose publications concerning metabolites of a prior art compound (compound SCH 48461)." Specifically, Sandoz alleged that the publications Merck withheld during prosecution of the RE'721 and RE'461 patents described "metabolic studies of SCH 48461 from which the examiner could determine the structure of metabolites of SCH48461, and that relevant metabolites were inherently formed by the preparation and administration of SCH 48461, as disclosed in [the PCT'048] patent." Sandoz also alleged that the Van Heek 1997 article had claimed the discovery of ezetimibe in conjunction with Dr. Rosenblum in 1995, and described the "large chemical synthesis program [that] evolved to discover a more potent backup compound for SCH 48461," including the addition of "[a] benzylic hydroxyl group … to SCH 53695 and several sites that were readily metabolized in SCH 48461 were blocked with fluorines resulting in [ezetimibe]." Sandoz additionally averred that the Dugar 1996 article, the Rosenblum I 1995 abstract, and the other prior art publications discussed above had specifically disclosed that two disclosed compounds, dubbed compound 57a and compound 58, were metabolites of SCH 48461 and thus inherently disclosed by the teachings of the prior art PCT'048 patent.

220. On September 3, 2013, the court ordered Sandoz to provide its ANDA to Merck by September 6, 2016, and ordered Merck to file its response to Sandoz's counterclaims on or before September 17, 2013.

221. On September 5, 2013, before any further proceedings or any substantive rulings in the case, Merck and Sandoz settled all issues in the patent infringement litigation. Judge Linares entered a consent judgment prohibiting Sandoz from launching generic Zetia before

April 25, 2017, and Sandoz admitted that the RE'421 patent was valid and would be infringed by its generic product. No other terms of the settlement were made public.

P. 2016: Glenmark/Par launches a generic form of Zetia; Merck does not

222. Glenmark's ANDA 78-560 received final FDA approval on June 26, 2015. In its final approval letter, the FDA reconfirmed that Glenmark was entitled to 180 days of market exclusivity upon launch.

223. On December 12, 2016, Glenmark/Par launched its generic Zetia, which its press release of that date described as "the first and only generic version" of Zetia in the United States.

224. From December 12, 2016, through June 12, 2017, Glenmark/Par's product was the only generic version of Zetia sold in the U.S. market. Without any other generic competition, Glenmark/Par priced its generic product at a modest discount of approximately 20-25% to branded Zetia and maintained that price until additional generics entered the market 180 days later. One year after multiple generics entered, the average WAC price was $0.22/ pill.

225. Merck refrained from launching an authorized generic version of Zetia during Glenmark/Par's 180-day exclusivity period. It did so pursuant to the no-AG pact in the parties' unlawful agreement.[35]

[35] Merck did not launch an authorized generic at the end of Glenmark/Par's 180-day exclusivity, in June 2017. But the economics for Merck *after* Glenmark/Par's 180-day exclusivity period were radically different than the economics Merck would have faced (absent the unlawful no-AG pact) *during* that exclusivity window. After the exclusivity period, Merck's authorized generic would have been one of at least seven generics on the market, competing for a margin driven down to near marginal cost. During Glenmark/Par's exclusivity window, as explained in detail above, a Merck-authorized generic would have been one of only two generics on the market, taking at least half the available sales at margins that would have yielded substantial profits.

226. In April 2017, during Glenmark/Par's exclusivity period, the patent protecting Vytorin expired. As Merck expected, multiple generics entered the market and launched generic Vytorin upon patent expiration.

Q. 2017: 180 days later, five more generics launch

227. On or about June 12, 2017 – the day Glenmark/Par's exclusivity expired – the FDA approved ANDAs for generic Zetia previously filed by seven competitor companies: Teva (ANDA 78-724), Sandoz (ANDA 203-931), Amneal (ANDA 208803), Apotex (ANDA 208332), Ohm Laboratories (ANDA 207311), Zydus (ANDA 204331), and Watson Laboratories (ANDA 200831).[36]

228. Five of these manufacturers – Teva, Sandoz, Amneal, Apotex, and Ohm Laboratories – launched a generic Zetia product in June 2017, shortly after receiving FDA approval. Zydus launched its generic Zetia product two months later, in August 2017. The seventh manufacturer, Watson Laboratories, had sold its generic drug business to Teva before June 2017 and so did not launch a generic Zetia product.

229. An eighth ANDA, filed by Aurobindo (ANDA 209838), was approved in August 2017. Aurobindo launched its generic Zetia product later that month. An additional ANDA, filed by Alkem Laboratories (ANDA 209234), was approved in December 2017.

R. Defendants Intended to and Did Harm Competition

230. The purpose and effect of the conduct by Defendants was to foreclose or severely limit generic competition to brand-name Zetia and Vytorin. By engaging in this scheme with Merck, Glenmark/Par did not simply delay its own sales of generic Zetia, but it blocked and delayed other potential competitors as well.

[36] The FDA approved Impax Laboratories, Inc.'s generic version of Vytorin in August 2017.

231. Whereas only brand-name Zetia was available to purchasers and consumers before December 2016, and only brand-name Zetia and Glenmark/Par's generic Zetia were available from December 2016 to June 2017, by July of 2017 there were six generics available on the market in addition to branded Zetia. By September of 2017 there were eight generics in addition to branded tablets.

232. Defendants' exclusionary conduct delayed, prevented, and impeded the sale of, and competition from, generic Zetia in the United States, and in Minnesota, and unlawfully enabled Merck to sell Zetia at artificially inflated prices. The conduct outlined above was exclusionary and an unreasonable restraint on competition.

233. Absent the no-AG agreement, Glenmark/Par would have entered the market with less expensive generic Zetia and Merck would have launched a competing authorized generic at prices well below the branded price for Zetia. Additional generics would have entered the market six months later and further driven down prices.

234. As a result of Defendants' illegal conduct, Plaintiff paid for Zetia at prices that were substantially greater than the prices it would have paid absent the illegal conduct alleged in this Complaint because: (1) it was deprived of an opportunity to purchase lower-priced generic Zetia instead of the brand-name Zetia at earlier times; and (2) the price of branded Zetia was artificially inflated by Defendants' illegal conduct. As a consequence, Plaintiff has sustained substantial losses and damage to its businesses and property in the form of overcharges paid for Zetia and Vytorin.

S. Effects on Interstate and Minnesota Commerce

235. At all material times, Zetia, manufactured and sold by Merck, was shipped across state lines and sold outside its state of manufacture. Merck and Glenmark/Par directed

the sale of Zetia, and its AB-rated generic equivalents, throughout the United States, and including into and/or through Minnesota.

236. At all relevant times, Plaintiff UHS was responsible for paying for Zetia and Vytorin obtained by UnitedHealthcare Insureds. For example, UHS is a party to agreements with pharmacy benefit managers and other third parties ("PBMs"), pursuant to which UHS is responsible for reimbursing, and makes direct payments to, PBMs for prescription drugs (including Zetia and equivalent generics) prescribed and dispensed to UnitedHealthcare Insureds throughout the United States. As a result of Defendants' unlawful conduct, third-party payors and other purchasers throughout the United States, and in Minnesota, paid supracompetitive prices for Zetia. UHS received invoices for payment, and made payments of several hundred million dollars for Zetia, and its AB-rated equivalents, at and from its headquarters in Hennepin County, Minnesota.

237. Defendants' unlawful activities, as described herein, affected the flow of interstate and Minnesota commerce and and had direct, substantial and reasonably foreseeable effects upon such trade and commerce.

238. But for Defendants' anticompetitive conduct, UHS and its DP Assignors would have (1) purchased and/or paid for lower-priced generic Zetia, instead of higher-priced branded Zetia (including purchasing generic Zetia along with simvastatin instead of branded Vytorin), during the period when Glenmark/Par delayed its entry to the market; (2) paid a lower price for Zetia during Glenmark's 180-day exclusivity period; (3) paid lower prices for Zetia, as a result of the entry of generics and an earlier date, sooner.

239. Before generic Zetia became available, Merck consistently increased prices for Zetia. Generic entrants typically price their products at a discount to the then-prevailing price

for the branded product. The first generic entrant generally prices at a modest discount to the branded price. When more than one generic manufacturers enter the market, generic prices fall rapidly and those generic products capture most of the branded's sales volumes. This is known as the generic "cliff." That is what happened with Zetia. Had generic entry occurred earlier, the first generic entrant would have discounted from a lower price point and competition would have rapidly driven prices down to competitive levels.

240. The only substitutes for Vytorin were separate prescriptions for Zetia and simvastatin. If a generic form of Zetia had been available earlier at prices comparable to the prices that were charged after Glenmark/Par's 180-day exclusivity period ($0.22/pill), and if Merck had continued to charge monopoly prices for branded Vytorin, UHS would have used available tools at is disposal to ensure that it paid less for Vytorin, including by excluding branded Vytorin from coverage in favor of the generic Zetia and simvastatin.

241. As a direct and proximate result of Defendants' conduct, UHS and its DP Assignors sustained substantial losses and damages to their business and property in the form of overcharges, the exact amount of which will be the subject of proof at trial. UHS and its DP Assignors allege that the anticompetitive effects of the conduct continued through at least 2019.

242. The economic harm that Defendants' conduct caused to UHS and its DP Assignors is measurable and quantifiable. Commonly used and well-accepted economic models can be used to measure both the existence and the amount of the supracompetitive charges paid by UHS and its DP Assignors.

T. Merck's Monopoly Power

243. Before December 12, 2016, Merck had monopoly power in the market for Zetia because it had 100% market share of Zetia and possessed the power to exclude competition and/or raise or maintain the price of Zetia at supracompetitive levels without losing enough sales to make supracompetitive prices unprofitable.

244. From December 12, 2016 to June 12, 2017, Merck and Glenmark/Par combined had substantial market power in the market for Zetia and its generic equivalent, because they shared 100% of the market and had the power to exclude competition and/or raise or maintain the price of ezetimibe at supracompetitive levels without losing enough sales to make supracompetitive prices unprofitable. Before December 12, 2016, a small but significant, non-transitory increase to the price of branded Zetia did not cause such a significant loss of sales that the price increase was not profitable. From December 12, 2016 through the end of all exclusivity, a small but significant, non-transitory increase in the price of generic Zetia would not have caused a significant loss of sales.

245. Branded Zetia does not exhibit significant, positive cross-elasticity of demand with respect to price with any other pharmaceutical product or treatment for hypercholesterolemia other than AB-rated generic versions of Zetia. That is, in the absence of AB-rated generics, a small but significant and non-transitory increase in the price of Zetia would not cause Merck to lose sufficient sales to other drugs to make the price increase unprofitable.

246. The pharmacological profile and mechanism of action for Zetia is different from other cholesterol drugs, such as statins. Statins cannot be automatically substituted for Zetia by pharmacists, and are not economic substitutes for, nor reasonably interchangeable with, Zetia.

As discussed above, approximately half of Zetia prescriptions were for statin-intolerant patients and the remaining half were sold as complements to statins.

247. Merck needed to control only branded Zetia and its AB-rated generic equivalents, and no other products, in order to maintain the price of Zetia profitably at supracompetitive prices. Only the market entry of competing, AB-rated generic versions would prevent Merck from maintaining extremely high and profitable prices for Zetia without losing substantial sales.

248. During Glenmark's 180-day exclusion period, Merck sold branded Zetia and Glenmark/Par sold generic Zetia at prices well in excess of marginal costs and in excess of the competitive price, and therefore, Merck and Glenmark/Par enjoyed high profit margins.

249. Defendants had, and exercised, the power to exclude generic competition to branded Zetia.

250. At all material times, high barriers to entry, including regulatory protections and high costs of entry and expansion, protected branded Zetia from the forces of price competition.

251. There is direct evidence of market power and anticompetitive effects available in this case sufficient to show the Defendants' ability to control the price of Zetia and generic Zetia, and/or to exclude relevant competitors, without the need to show the relevant antitrust markets. The direct evidence consists of, *inter alia*, the following facts: (a) generic Zetia would have entered the market at a much earlier date, at a substantial discount to branded Zetia, but for Defendants' anticompetitive conduct; (b) Merck's gross margin on Zetia (including the costs of ongoing research/development and marketing) at all relevant times was

very high; and (c) Merck never lowered the price of Zetia to the competitive level in response to the pricing of other brand or generic drugs.

252. To the extent that Plaintiff is required to prove monopoly power circumstantially by first defining the relevant product market, Plaintiff alleges a relevant product market for antitrust purposes that consists of Zetia and its AB-rated generic equivalents. The relevant geographic market is the United States including, but not limited to, Minnesota.

U. Accrual and Tolling of The Statute of Limitations

253. Each time that UHS and its DP Assignors paid an overcharge for branded or generic Zetia or Vytorin, a new cause of action accrued for that overcharge, *ie.*, each time payment was made at a price higher than would have been paid absent Defendants' unlawful conduct.

254. In addition, prior to the filing of this Complaint, UHS and DP Assignors were absent class members under numerous class action complaints filed in January 2018.[37] Pursuant to the United States Supreme Court decision in *American Pipe Construction Co. v. Utah*, 414 U.S. 538 (1974) and its progeny, the class action complaints tolled the applicable statute of limitations as to the claims of UHS and DP Assignors (and all other putative class members). Accordingly, Plaintiff is entitled to recover overcharges on all purchases and/or payments made starting at least four years prior to the filing of those class cases, *i.e.*, January 2014 and later.

[37] *See, e.g., FWK Holdings, LLC v. Merck & Co., Inc. et al*., 2:18-cv-00023-RBS-DEM; *Fraternal Order of Police, et al, v. Merck & Co., Inc. et al.*, 2:18-cv-00035-RBS-DEM; and all other class actions consolidated and/or coordinated in MDL No. 2836 (2:18-md-02836-RBS-DEM) pending in the Eastern District of Virgina.

255. In addition, Plaintiff is entitled to recover damages on purchases made prior to January 2014, because Defendants fraudulently concealed their unlawful conduct and Plaintiff did not and could not have discovered that conduct by the exercise of reasonable diligence prior to December 2016, thereby tolling the statute. Merck's payment to Glenmark in the form of a no-AG promise was not discoverable until after Glenmark launched its generic Zetia in December 2016 and Merck did not launch an authorized generic. Merck and Glenmark had previously disclosed only cursory information about their reverse payment agreement.

256. Defendants' scheme was self-concealing and, in addition, Defendants actively concealed their conspiracy to avoid detection.

257. Defendants wrongfully and affirmatively concealed the existence of their ongoing combination and conspiracy from Plaintiffs by, among other things:

a. Concealing the fact of Merck's agreement not to launch a competing authorized generic Zetia product in exchange for Glenmark/Par's agreement not to market its competing generic product until December 12, 2016;

b. Concealing the fact that the purpose of the no-AG agreement was to provide compensation to Glenmark/Par in connection with the settlement of the patent litigation and the December 2016 entry date for Glenmark/Par's generic product; and

c. Filing documents with the United States Securities and Exchange Commission that failed to disclose the existence or nature of the payments made.

258. Defendants' scheme was self-concealing and, in addition, Defendants actively concealed their conspiracy to avoid detection.

259. Because the scheme and conspiracy were both self-concealing and affirmatively concealed by the Defendants, Plaintiff had no knowledge of the conspiracy until December

2016 and could not have uncovered it before that date through the exercise of reasonable diligence, which Plaintiff exercised.

260. Plaintiff also lacked the facts and information necessary to form a good faith basis for believing that any legal violations had occurred.

VII. CLAIMS FOR RELIEF

COUNT ONE: VIOLATION OF 15 U.S.C. § 1
(Against Merck and Glenmark - Damages/Monetary Relief with Respect to Assignor Direct Purchases)

261. UHS incorporates by reference the allegations in paragraphs 1 through 249, above.

262. On or about May 10, 2010, Merck and Glenmark/Par entered into a reverse-payment agreement pursuant the purpose and effect of which was to (a) allocate sales of Zetia in the United States to Merck; (b) prevent the sale of a generic version of Zetia in the United States, thereby protecting Zetia and Vytorin from generic competition for as many as five years; and (c) fix the price for Zetia at a supracompetitive price.

263. By entering into the unlawful agreement, Merck and Glenmark/Par unlawfully conspired in restraint of trade and committed a violation of the Sherman Act.

264. Defendants' agreement is a horizontal market allocation and price-fixing agreement between actual or potential competitors and thus is a *per se* violation of the Sherman Act.

265. In the alternative, Defendants' agreement is an unreasonable restraint of trade when viewed under a rule of reason analysis. The agreement was not reasonably necessary to accomplish any procompetitive objective. The agreement included a reverse payment from Merck to Glenmark/Par that exceeded Merck's anticipated litigation costs to continue pursuing

the patent litigation. Moreover, any potential justification that Defendants could assert will not outweigh the substantial anticompetitive effect of their agreement. Even if Defendants could assert a legitimate, non-pretextual, procompetitive business justification for the reverse payment agreement, the anticompetitive effects of the agreement would substantially outweigh any supposed pro-competitive effects of the agreement.

266. But for Defendants' antitrust violation, generic competition to Zetia would have begun as early as December 2011. UHS and its DP Assignors would have paid lower prices for generic Zetia from December 2011 until at least mid-2019. As a result of Defendants' antitrust violation, UHS and its DP Assignors have been injured in their business or property.

267. UHS, by virtue of its assignments from DP Assignors, seeks and is entitled to treble damages under Section 4 of the Clayton Act, 15 U.S.C. § 15, for all overcharges proximately caused by the antitrust violation(s) alleged above. Such damages have been suffered in an amount to be proven at trial.

COUNT TWO: VIOLATION OF 15 U.S.C. § 2
(Against Merck and Glenmark - Damages/Monetary Relief with Respect to Assignor Direct Purchases)

268. UHS incorporates by reference the allegations in paragraphs 1 through 249, above.

269. At all relevant times, Merck possessed monopoly power in the relevant market.

270. Merck and Glenmark/Par conspired to achieve or maintain Merck's monopoly power and committed overt acts in furtherance of their unlawful conspiracy.

271. Merck and Glenmark/Par each had a specific intent to achieve or maintain monopoly power in the relevant market. By paying Glenmark/Par hundreds of millions of dollars to delay the launch of its generic product, Merck manifested a specific intent to maintain

its monopoly from at least 2011 to 2016. By accepting Merck's payment, Glenmark/Par manifested its specific intent to allow Merck to maintain its monopoly from at least 2011 to 2016, and its specific intent to obtain market power as the sole source of generic Zetia from December 2016 to June 2017.

272. As a result of Defendants' antitrust violation, UHS and its DP Assignors have been injured in their business or property and continue to suffer such injury. Their injury consists of having paid and continuing to pay higher prices for Zetia and its AB-rated equivalents and for Vytorin between at least December 2011 and the present. Such overcharges are the type of injury the antitrust laws were designed to prevent and flow from that which makes Defendants' acts unlawful.

273. UHS, by virtue of its assignments from DP Assignors, seeks treble damages under Section 4 of the Clayton Act, 15 U.S.C. § 15, for all overcharges proximately caused by the antitrust violation(s) alleged above. Such damages have been suffered in an amount to be proven at trial.

COUNT THREE: VIOLATION OF MINNESOTA ANTITRUST LAW
(Conspiracy in Restraint of Trade Against All Defendants –
Damages/Monetary Relief for Indirect Purchases/Payments)

274. UHS incorporates by reference the allegations in paragraphs 1 through 249, above.

275. On or about May 10, 2010, Merck and Glenmark/Par entered into a reverse-payment agreement, the purpose and effect of which was to (a) allocate sales of Zetia in the United States to Merck; (b) prevent the sale of a generic version of Zetia in the United States, thereby protecting Zetia and Vytorin from generic competition for as many as five years; and (c) fix the

price for Zetia at a supracompetitive price. The reverse-payment agreement violated Minnesota Antitrust Law.

276. Defendants' agreement was a horizontal market allocation and price-fixing agreement between actual or potential competitors and thus is a *per se* violation of the Minnesota Antitrust Law.

277. In the alternative, the reverse payment agreement was an unreasonable restraint of trade when viewed under a rule of reason analysis because the agreement was not reasonably necessary to accomplish any procompetitive objective and any potential justification would be substantially outweighed by its anticompetitive effects.

278. But for Defendants' antitrust violation, generic competition to Zetia would have begun as early as December 2011. UHS would have paid lower prices for generic Zetia from December 2011 until at least mid-2019.

279. During the relevant period, through either Defendants themselves or the regional and national distributors and retailers that they have engaged for the sale of the drugs at issue, many millions of dollars' worth of the drugs at issue have been, and continue to be, sold and/or paid for in Minnesota each year.

280. The anticompetitive acts by Defendants exerted a substantial and foreseeable effect on Minnesota commerce by artificially raising and fixing prices for drugs at issue, as were paid in, and/or out from, Minnesota, and otherwise injuring corporations and persons located in Minnesota.

281. As a proximate result of Defendants' violation of Minnesota Antitrust Law, UHS has been harmed by paying artificially inflated, supra-competitive prices for Zetia and

Vytorin dispensed to insureds throughout the United States, and UHS has suffered damages in an amount to be proven at trial.

282. UHS seeks treble damages under Minnesota law for all overcharges incurred and paid by UHS as a result of Defendants' conduct, as well as attorneys' fees and costs, and all other forms of relief available under Minn. Stat. § 325D.49, *et seq.*

COUNT FOUR: VIOLATION OF MINNESOTA ANTITRUST LAW (Monopolization/Conspiracy to Monopolize Against All Defendants - Damages/Monetary Relief for Indirect Purchases/Payments)

283. UHS incorporates by reference the allegations in paragraphs 1 through 249, above.

284. At all relevant times, Merck possessed monopoly power in the relevant market.

285. Merck and Glenmark/Par conspired to achieve or maintain Merck's monopoly power and committed overt acts in furtherance of their unlawful conspiracy.

286. Merck and Glenmark/Par each had a specific intent to achieve or maintain monopoly power in the relevant market. By paying Glenmark/Par hundreds of millions of dollars to delay the launch of its generic product, Merck manifested a specific intent to maintain its monopoly from at least 2011 to 2016. By accepting Merck's payment, Glenmark/Par manifested its specific intent to allow Merck to maintain its monopoly from at least 2011 to 2016, and its specific intent to obtain market power as the sole source of generic Zetia from December 2016 to June 2017.

287. Defendants' conduct constitutes an attempt to establish, maintain, or use monopoly power of a part of trade or commerce for the purpose of affecting competition or controlling, fixing, or maintaining prices, in violation of Minnesota Antitrust Law, Minn. Stat. § 325D.52.

288. During the relevant period, through either Defendants themselves or the regional and national distributors and retailers that they have engaged for the sale of the drugs at issue, many millions of dollars' worth of the drugs at issue have been, and continue to be, sold and/or paid for in Minnesota each year.

289. The anticompetitive acts by Defendants had a substantial and foreseeable effect on Minnesota commerce by artificially raising and fixing prices for the drugs at issue, as they were paid in, and/or out from, Minnesota, and otherwise injuring corporations and persons located in Minnesota.

290. Defendants' unlawful activities, as described in this Complaint, affected both intrastate commerce in Minnesota and interstate commerce flowing in to or out from Minnesota, and had direct, substantial and reasonably foreseeable effects upon trade and commerce in Minnesota.

291. As a proximate result of Defendants' violation of Minnesota Antitrust Law, UHS has been harmed by paying artificially inflated, supra-competitive prices for Zetia dispensed to insureds throughout the United States, and UHS has suffered damages in an amount to be proven at trial.

292. UHS seeks treble damages under Minnesota law for all overcharges incurred and paid by UHS as a result of Defendants' conduct, as well as attorneys' fees and costs, and all other forms of relief available under Minn. Stat. § 325D.49, *et seq.*

COUNT FIVE: VIOLATION OF VARIOUS STATE ANTITRUST AND CONSUMER PROTECTION LAWS
(Against All Defendants - Damages/Monetary Relief for Indirect Purchases/Payments, In the Alternative)

293. UHS incorporates by reference the allegations in paragraphs 1 through 249, above.

294. This claim for relief is pleaded in the alternative to the Third and Fourth Claims for Relief, in the event that the Court disagrees that all of UHS's statutory claims for damages and/or monetary relief for all payments for drugs dispensed to UnitedHealthcare Insureds (to the extent made indirectly) are governed by Minnesota law.

295. UHS asserts that, by engaging in the anticompetitive conduct alleged above, Defendants have alternatively violated the antitrust and competition statutes of all states and territories that may provide any relief for indirect purchasers/payors, including but not limited to each the following such laws (provided here as exemplars):[38]

a. Arizona Rev. Stat. §§ 44-1403, *et seq.*,

b. Cal. Bus. & Prof. Code §§ 16600, *et seq.*, Cal. Bus. & Prof. Code §§ 17200, *et seq.*, and the California common law,

c. Conn. Gen. Stat. Ann. §§ 35-24, *et seq*.,

d. D.C. Code §§ 28-4503, *et seq.*,

e. Fla. Stat. §§ 501.201, *et seq.*,

f. Hawaii Code §§ 480, *et seq.*,

g. 740 Ill. Comp. Stat. 10/3, *et seq.*,

h. Iowa Code §§ 553.5, *et seq*.,

i. Kan. Stat. Ann. §§ 50-101, *et seq*.,

j. Mass. Gen. L. Ch. 93A, *et seq.*,

k. Md. Code, Com. Law §§ 11-204, *et seq.*,

l. Me. Rev. Stat. Ann. 10, §§ 1102, *et seq.*,

[38] UHS reserves all rights to assert any and all other state laws that may provide any relief to indirect purchasers/payors (whether conferred by antitrust, unfair deceptive trade practices, consumer protection statutes, or the like).

m. Mich. Comp. Laws Ann. §§ 445.773, *et seq.*,

n. Minn. Stat. §§ 325D.52, *et seq.*,

o. Miss. Code Ann. §§ 75-21-3, *et seq.*,

p. Neb. Code Ann. §§ 59-802, *et seq.*,

q. Nev. Rev. Stat. Ann. §§ 598A.060, *et seq.*,

r. N.C. Gen. Stat. §§ 75-2.1, *et seq.*,

s. N.D. Cent. Code §§ 51-08.1-03, *et seq*.,

t. N.H. Rev. Stat. Ann. §§ 356.1, *et seq*.,

u. N.M. Stat. Ann. §§ 57-1-2, *et seq*.,

v. New York Gen. Bus. Law §§ 340, *et seq.*,

w. Or. Rev. Stat. §§ 646.705, *et seq*.,

x. 10 L.P.R.A. §§ 257, *et seq.*,

y. R.I. Gen. Laws §§ 6-36-1, *et seq*.,

z. S.D. Codified Laws §§ 37-1-3.2, *et seq*.,

aa. Utah Code Ann. §§ 76-10-911, *et seq*.,

bb. Tenn. Code Ann. §§ 47-25-101, e*t seq.*,

cc. Vt. Stat. Ann. 9, §§ 2453, *et seq*.,

dd. W.Va. Code §§ 47-18-4, *et seq.*, and

ee. Wis. Stat. §§ 133.03, *et seq*.

296. In addition, Defendants' conduct further constitutes unfair competition or unfair, unlawful, unconscionable, deceptive, and/or fraudulent acts or practices in violation of the consumer protection statutes including, but not limited to each of the following states and territories:

a. Ark. Code §§ 4-88-101, *et seq*.,

b. Ariz. Code §§ 44-1522, *et seq*.,

c. Cal. Bus. & Prof. Code §§ 17200, *et seq*.,

d. Colo. Rev. Stat §§ 6-1-105, *et seq*.,

e. D.C. Code §§ 28-3901, *et seq*.,

f. Fla. Stat. §§ 501.201, *et seq*.,

g. Idaho Code §§ 48-601, *et seq*.,

h. 815 ILCS §§ 505/1, *et seq*.,

i. Ind. Code §§ 24-5-0.5-1, *et seq*.,

j. Kan. Stat. §§ 50-623, *et seq*.,

k. La. Rev. Stat. Ann. §§ 51:1401, *et seq*.,

l. 5 Me. Rev. Stat. §§ 207, *et seq*.,

m. Mass. Ann. Laws ch. 93A, *et seq*.,

n. Mich. Stat. §§ 445.901, *et seq*.,

o. Minn. Stat. §§ 325D.43, *et. seq*., Minn. Stat. §§ 325F.69, *et seq*., and Minn. Stat. §§ 8.31, *et seq*.,

p. Miss. Code. Ann. §§ 75-24-1, *et seq*.,

q. Missouri Stat. §§ 407.010, *et seq*.,

r. Neb. Rev. Stat. §§ 59-1601, *et seq*.,

s. Nev. Rev. Stat. §§ 598.0903, *et seq*.,

t. N.H. Rev. Stat. §§ 358-A:1, *et seq*.,

u. N.M. Stat. §§ 57-12-1, *et seq*.,

v. N.Y. Gen. Bus. Law §§ 349, *et seq*.,

w. N.C. Gen. Stat. §§ 75-1.1, *et seq*.,

x. N.D. Cent. Code §§ 51-15-01, *et seq*.,

y. Or. Rev. Stat. §§ 646.605, *et seq*.,

z. 73 Pa. Stat. Ann. §§ 201-1, *et seq*.,

aa. S.C. Stat. Ann. §§ 39-5-10, *et seq*.,

bb. S.D. Code Laws §§ 37-24-1, *et seq*.,

cc. Utah Code §§ 13-11-1, *et seq*.,

dd. 9 Vt. §§ 2451, *et seq*.,

ee. Va. Code Ann. §§ 59.1-196, *et seq*.,

ff. W.Va. Code §§ 46A-6-101, *et seq*.,

gg. Wis. Stat. §§ 100.18; Wis. Stat. §§ 100.20, *et. seq*., and

hh. Wyo. Stat. Ann. §§ 40-12-101, *et seq*.

297. The unlawful acts by Defendants had, and continue to have, a substantial and foreseeable effect on the commerce of each above State and territory by artificially raising and fixing prices for the drugs at issue paid for, and/or dispensed in each State or territory.

298. Defendants' unlawful activities, as described in this Complaint, affected both intrastate commerce and interstate commerce flowing in to or out from each of the above States and territories, and had direct, substantial and reasonably foreseeable effects upon trade and commerce in each respective State or territory.

299. During the relevant period, through either Defendants themselves or the regional and national distributors and retailers that they have engaged for the sale of the drugs at issue, many millions of dollars' worth of those drugs have been, and continue to be, sold in each of the above States and territories every year.

300. As a direct and proximate result of Defendants' violation of each of the foregoing laws, UHS has been harmed by paying artificially inflated, supra-competitive prices for the drugs dispensed to insureds throughout the United States, and UHS has suffered damages in an amount to be proven at trial.

301. There was and is a gross and unconscionable disparity between the price that UHS paid for the drugs at issue, and the value received, given that more cheaply priced drugs should have been available, and would have been available, absent Defendants' illegal conduct.

302. UHS has been injured in its business and property by paying more for the drugs at issue than in the absence of Defendants' unlawful conduct and violation of the foregoing laws.

303. Defendants' conduct in violation of each of the foregoing laws was done knowingly, willfully, and flagrantly.

304. UHS seeks damages, trebled or multiplied to the full extent permitted by each of the foregoing States and territories, for all overcharges incurred and paid by UHS as a result of Defendants' conduct, restitution, as well as attorneys' fees and costs, and all other forms of relief available.

COUNT SIX: UNJUST ENRICHMENT
(Against Merck and Glenmark - Damages/Monetary Relief with Respect to All UHS and DP Assignor Purchases/Payments)

305. UHS incorporates by reference the allegations in paragraphs 1 through 249, above.

306. To the extent required, this claim is pleaded in the alternative to the other claims and/or causes of action in this Complaint.

307. Defendants have unlawfully benefited from their sales of Zetia because of the unlawful and inequitable acts alleged in this Complaint. Defendants unlawfully overcharged UHS and DP Assignors, who paid for Zetia at prices that were more than they would have been but for the unlawful actions alleged above.

308. Defendants' financial benefits resulting from their unlawful and inequitable acts are traceable to overpayments by UHS and DP Assignors.

309. To their economic detriment, UHS and DP Assignors have conferred upon Defendants an economic benefit, in the nature of profits resulting from unlawful overcharges.

310. Defendants have been enriched by revenue resulting from unlawful overcharges for the drugs at issue while UHS and DP Assignors have suffered a loss or impoverishment by the overcharges they paid, imposed through Defendants' unlawful conduct. Defendants' enrichment and the loss/impoverishment to UHS and DP Assignors are connected.

311. There is no justification for Defendants' retention of, and enrichment from, the benefits they received, which caused a loss or impoverishment to UHS and DP Assignors, having paid supracompetitive prices that inured to Defendants' benefit, and it would be inequitable for Defendants to retain any revenue gained from their unlawful overcharges.

312. UHS and DP Assignors did not interfere with Defendants' affairs in any manner that conferred these benefits upon Defendants.

313. The benefits conferred upon Defendants was not gratuitous, in that they constituted revenue created by unlawful overcharges arising from Defendants' illegal and unfair actions to inflate the prices of the subject drugs.

314. The benefits conferred upon Defendants are measurable, in that the revenues Defendants have earned due to their unlawful overcharges on the drugs at issue are ascertainable by review of sales and/or payment records.

315. As to payments by UHS, it would be futile for UHS to seek a remedy from any party with whom they have privity of contract. Defendants have paid no consideration to any other person for any of the unlawful benefits they received indirectly from UHS with respect to Defendants' sales of the drugs at issue.

316. As to payments by UHS, it would be futile for UHS to seek to exhaust any remedy against the immediate intermediary in the chain of distribution from which they indirectly purchased or paid for the drugs at issue, as the intermediaries are not liable and cannot reasonably be expected to compensate UHS for Defendants' unlawful conduct.

317. The economic benefit of overcharges and monopoly profits derived by Defendants through charging supracompetitive and artificially inflated prices for the drugs at issue are a direct and proximate result of Defendants' unlawful practices.

318. The financial benefits derived by Defendants rightfully belong to UHS, because UHS and its DP Assignors paid supracompetitive prices during the relevant period, inuring to the benefit of Defendants.

319. It would be inequitable under unjust enrichment principles of Minnesota, or alternatively, all States and territories in the United States except Ohio and Indiana, for Defendants to be permitted to retain any of the overcharges derived from Defendants' unlawful, unfair and unconscionable methods, acts, and trade practices alleged in this Complaint.

320. Defendants are aware of and appreciate the benefits bestowed upon them by UHS and its DP Assignors. Defendants consciously accepted the benefits and continue to do so as of the date of this filing.

321. Defendants should be compelled to disgorge in a common fund for the benefit of UHS all unlawful or inequitable proceeds received from its sales of the drugs at issue.

322. A constructive trust should be imposed upon all unlawful or inequitable sums received by Defendants traceable to the payments made by UHS and DP Assignors for the drugs at issue.

323. There is no adequate remedy at law.

324. By engaging in the foregoing unlawful or inequitable conduct depriving UHS and DP Assignors of lower prices for the subject drugs and forcing them to pay higher prices, Defendants have been unjustly enriched in violation of the common law of Minnesota, or alternatively, all States and territories in the United States except Ohio and Indiana

DEMAND FOR JUDGMENT

WHEREFORE, UHS prays for judgment against Defendants and for the following relief:

A. A declaration that the conduct alleged herein is in violation of Sections 1 and 2 of the Sherman Act;

B. A declaration that the conduct alleged herein is in violation of Minnesota Antitrust Law;

C. A declaration that the conduct alleged herein is in violation of the state statutes set forth above, and the common law of unjust enrichment of the states and territories set forth above;

D. An award to UHS of actual, consequential, compensatory, treble, punitive, and/or other damages, in an amount to be proven at trial, including pre- and post- judgment interest at the statutory rates;

E. An award to UHS of equitable relief in the nature of disgorgement, restitution, and the creation of a constructive trust to remedy Defendants' unjust enrichment;

F. An award to UHS of its reasonable costs and expenses, including attorneys' fees; and

G. An award of all other legal or equitable relief as the Court deems just and proper.

JURY DEMAND

Plaintiff demands a jury trial on all claims so triable under Federal Rule of Civil Procedure Rule 38(b).

DATED: February 9, 2022

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